



FAIR DATA SHARING & DATA CARING IN THE DIGITALIZED ERA: ASPIRATIONS, REALITIES & LEGAL CLASHES IN THE HEALTH & LIFE SCIENCES

Abstract of presentation at Stanford Law School

Minssen, Timo

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BIO LAW LAPALOOZA

March 22nd & 23rd
Stanford Law School

2018



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Schedule

Thursday, March 22

12:00 **Lunch** Welcomes, Intros Crown Quad, Rooms 320 D and E

Plenary I Mainly FDA & IP Crown Quad, FIR Building, Rm 80 (Moot Court Rm)

1:00	Darnovsky/Obasogie	Bioethics v Biopolitics
1:30	Zettler	Public Health Perspective in FDA
1:45	Sachs	De-Linking Drug Reimbursement from FDA Approval
2:00	Heled	Follow-On Biologics – Set up to Fail
2:15	Rutschman	IP Preparedness for Outbreak Diseases
2:30	Ouellette	Bayh-Dole's Effects on Researchers' Incentives
2:45	Bair	IP's Lost Einstein's

3:00 **Break**

Plenary II Mainly Medicine Crown Quad, FIR Building, Room 80 (Moot Court Room)

3:30	Sage	De-medicalizing Health Care
3:45	Konnoth	Medicalization and New Civil Rights
4:00	Wolitz	States and Drug Prices
4:15	Vertinsky	Corporations and the Opioid Epidemic
4:30	Lamkin	Legitimate Medicine in an Era of Consumerism
4:45	Rogers	Regulating the Dead: From Past to Present
5:00	Bobinski	Conscience Clauses
5:15	Grossman	The History of the Struggle for Medical Marijuana Access

6:00 **Dinner** Hank's house – 739 Santa Ynez St. (10 min walk)

Friday, March 23

8:00 **Breakfast** Crown Quad, "Link" Building, Room 270 (Manning Lounge)

Concurrent IA Patents Crown Quad, "Link" Building, Room 270 (Manning Lounge)

8:30	Dreyfuss/Nicol	Myriad in the US and Australia
8:45	Bubela	University Patent Litigation
9:00	Holman	Monoclonals and Written Description
9:15	Feldman	Evergreening in the Biggest Pharmaceutical Companies
9:30	Simon	Contextualizing the Information Facilitating Function of Patents
9:45	Karshtedt	FDA, Patents, and Generics

Concurrent IB	Mainly Medicine	Crown Quad, Room 320 D
8:30	Bloche	Technological Innovation and Clinical Costs
8:45	Weithorn	Physician Aid in Dying for the Mentally or Psychologically Distressed
9:00	Casebeer	Normative Considerations of "Identity" in Neurotechnology
9:30	Griffin	Brain Injury and Technology
9:15	Parasidis	Whole Exome Sequencing in Military Health
9:45	Marcon	Injecting Doubt: Naturopaths and Anti-Vaccination

10:00 **Break** Crown Quad, "Link" Building, Room 270 (Manning Lounge)

Concurrent IIA Big Data + Brain Crown Quad, "Link" Building, Room 270 (Manning Lounge)

10:30	Ossorio	Regulating Predictive Algorithms in 'Omics Assays
10:45	Wolf	Big Data, Research Risks, and State Law
11:00	Hoffman	Age and Gender Effects on Third Party Punishment

11:15	Denno	Neuroscience and the Personalization of Criminal Law
11:30	Nadler	Teaching Law and Neuroscience
11:45	Shen	A NeuroLaw Clinic

Concurrent IIB	Reproduction	Crown Quad, Room 320 D
10:30	Carbone	Lawyers' Role in ART Contracts of Uncertain Enforceability
10:45	Daar	Embryo Mosaicism and ART Practice
11:00	Fox	Sperm Donation Errors and Race
11:15	Mohapatra	Considering Pregnant Women in Maternal/Fetal Surgery
11:30	Torrance	GINA and Edited Genomes
11:45	Oberman	Abortion Law in the 21 st Century

12:00	Lunch	Crown Quad, "Link" Building, Room 270 (Manning Lounge)
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Plenary III	Mainly Brain	Crown Quad, FIR Building, Rm 190
1:00	Murphy	Memory Detection
1:15	Moriarty	Neuroscience Lie Detection
1:30	Grey	Legal Significance of Research Finding Sex Differences in the Brain
1:45	Ram	Forensic Biobanking and Family Searching
2:00	Seaman	Cyberpsychology
2:15	Bloch	Using Virtual Reality to Prevent Prosecutorial Misconduct
2:30	Drobac	Brain Science and the Law of Consent
2:45	Maurer	Synthetic Biologists and the Idea of Self-Governance

3:00	Break
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Plenary IV	Discrim/Datashare	Crown Quad, FIR Building, Rm 190
3:30	Prince	Genetic Anti-Discrimination in Life & Income Replacement Ins
3:45	Arias	Alzheimer Disease, Clinical Biomarkers, & Ins./Employment Risks
4:00	Wagner	Return of Research Results and the Loss of a Chance Doctrine
4:15	Sherkow	Genetic Data and Adaptive Immunoreceptor Repertoire Projects
4:30	Minssen	Fair Data Sharing and Data Caring in the Digitized Era
4:45	Cook-Deegan	Data Hoarding in Genomics Can Kill: What Can We Do About It?
5:00	[open slot somewhere on this panel]	
5:15	Concluding Remarks	

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THE NEXT STAGE OF ALZHEIMER'S DISEASE AND PRECLINICAL BIOMARKERS: AN EVALUATION OF EMPLOYMENT AND INSURANCE DISCRIMINATION RISKS BASED ON BIOMARKER STATUS

Jalayne Arias*

*UCSF School of Medicine

This presentation will report data from a study that examines the legal, ethical and social consequences of preclinical biomarkers in Alzheimer's disease. Preclinical Alzheimer's disease biomarkers are measures of amyloid or tau that correlate with the "hallmark" plaques and tangles of the disease. These biomarkers indicate the presence of disease pathology and are detectable up to 20 years before symptoms present. While the preclinical use of biomarkers has been restricted to research purposes, leading clinical trials rely on the hypothesis that the best hope for disease modifying therapy relies on treatment before symptoms emerge. Therefore, biomarkers will be critical to identifying individuals who are most likely to benefit from preclinical treatment. Conversely, biomarkers may raise novel legal and ethical issues

This study uses empirical legal research methods and semi-structured interviews with physicians (n=17) and human resource managers (n=9). Here we will report on data showing gaps in employment and insurance anti-discrimination legal protections. We compare these results with physician and human resource manager perspectives on the potential consequences of biomarker status in the context of employment and insurance. The presentation will describe likely outcomes of future patients who receive their biomarker status in the context of employment and insurance. This descriptive data will highlight the need for a re-evaluation of current legal standards. The presentation will close by identifying research and policy goals for developing anti-discrimination protections tailored to Alzheimer's disease biomarker status.

IP'S LOST EINSTEINS

Stephanie Plamondon Bair*

*BYU Law School

Intellectual property offers private incentives to artists and inventors. Its goal is to spur advances in the arts and sciences that wouldn't otherwise happen. But though intellectual property is concerned with *how much* innovation society produces, in its current form it has little to say about *who* is doing the innovative work—and reaping the attendant rewards.

This is a problem. Accumulating evidence shows that the benefits of owning intellectual property accrue disproportionately to advantaged groups. One recent study, for instance, finds that a poor child with outstanding math skills has less of a chance of ever holding a patent than a rich child, even when the rich child is much worse at math. A review of copyright registrations by Robert Brauneis and Dotan Oliar reveals that white authors are overrepresented in the copyright system, while Hispanic authors in particular suffer extreme underrepresentation. And Dan Burk has drawn attention to the "gender gap" in patent law, pointing out that women engineers and scientists hold a disproportionately small number of patents relative to the men they work with. These imbalances don't just hurt those denied opportunities to participate in the IP system—society's "lost Einsteins" as they have been called. The general public also suffers as we miss out on the collective benefit of all the innovations and artistic advances that might have been.

What causes these disparities, and what should we do about it? Those who have explored the topic have implicated unequal opportunity, bias, IP doctrines that reward typically male risk-taking behaviors—the usual cultural suspects. But here, I'd like to propose that something beyond culture and socialization might also be responsible for many of our lost Einsteins. Recent work in the neurosciences suggests that the realities disadvantaged groups often contend with may affect their decision-making processes in ways that impact their ability to innovate. Specifically, when people are chronically stressed, when people are chronically sleep-deprived, they are less likely to think and act in ways that lead to creative breakthroughs.

These findings are troubling for two reasons. First, because the psychological and neural aspects of innovation are less easily observed than some of the previously-identified cultural factors (like bias in the workplace), they run the risk of being overlooked. Second, because external factors like stress and sleep

deprivation operate on the individual in ways that change decision-making, there is a danger that outside observers will wrongly chalk up resulting behaviors to an inherent failing or lack of talent. This, in turn, feeds the cultural fire of stereotype and bias.

The neural aspect of the lost Einstein phenomenon also suggests that we need to think much more broadly and aggressively about how to solve innovative disparities. Though we should continue to tackle cultural issues like bias and IP doctrines that disadvantage certain groups, we should also consider a more holistic approach that addresses the lives and needs of individual inventors.

HARNESSING VIRTUAL REALITY TO PREVENT PROSECUTORIAL MISCONDUCT

Kate E. Bloch*

*UC Hastings College of Law

It was the confession of a man facing death, but not the man convicted of the capital crime.¹ This confession came from the terminally ill prosecutor, whose suppression of evidence many years earlier had helped put the accused on death row.² In *Connick v. Thompson*, the prosecutor admitted deliberately withholding evidence, evidence that would subsequently lead to the exoneration of the accused.³

Prosecutorial failure to disclose material exculpatory evidence can violate the U.S. Constitution and undermine justice. The Supreme Court's decision in *Brady v. Maryland*, which gave voice to this constitutional requirement, dates to 1963, more than half a century ago.⁴ Yet, court cases, like *Connick*, and related investigations bear witness to the continuing practice and detrimental consequences of such prosecutorial failure to disclose.⁵ As *Brady* focuses on the consequence to the accused, rather than on the mental state of the prosecutor, *Brady* condemns the failure to disclose whether it is in good or bad faith.⁶

Recent scholarship on *Brady* error suggests that prosecutorial failure to disclose may often stem from circumstances or cognitive processes that undermine the prosecutor's awareness of the exculpatory nature of the evidence at issue or the importance of disclosing it.⁷ Confirmation bias is an example of this type of process.⁸ Under the influence of confirmation bias, an individual, generally without conscious awareness, selects and adopts evidence that supports the individual's pre-existing viewpoint and underweights or rejects evidence contrary to this pre-existing perspective.⁹ Such bias can cause prosecutors to miss the exculpatory quality of evidence or to discount its value, which can lead to failure to disclose.¹⁰

Finding effective approaches for disrupting such cognitive bias may be key to truncating the long trajectory of *Brady* constitutional violations. Advances in cognitive science research suggest that perspective-taking

¹ *Connick v. Thompson*, 563 U.S. 61, 83-90 (2011).

² *Id.*

³ *Id.*

⁴ *Brady v. Maryland*, 373 U.S. 83 (1963).

⁵ See e.g., Ken Armstrong and Maurice Possley, *The verdict: Dishonor*, Chicago Tribune (Jan. 11, 1999) (last accessed Jan. 15, 2018) available at <http://www.chicagotribune.com/news/watchdog/chi-020103trial1-story.html>.

⁶ *Brady v. Maryland*, 373 U.S. 83, 87 (1963) ("We now hold that the suppression by the prosecution of evidence favorable to an accused upon request violates due process where the evidence is material either to guilt or to punishment, irrespective of the good faith or bad faith of the prosecution.").

⁷ For discussions of cognitive bias research applied to prosecutorial *Brady* decision making, see e.g., Hadar Aviram, *Legally Blind: Hyperadversarialism, Brady Violations and the Prosecutorial Organizational Culture*, 87 ST. JOHN'S L. REV. 1 (2013); Alafair S. Burke, *Improving Prosecutorial Decisionmaking: Some Lessons of Cognitive Science*, 47 WM. & MARY L. REV. 1587, 1593 (2006) ("This Article explores four related but separate aspects of cognitive bias that can contribute to imperfect theory formation and maintenance: confirmation bias, selective information processing, belief perseverance, and the avoidance of cognitive dissonance."); Ellen Yaroshesky, *Why Do Brady Violations Happen: Cognitive Bias and Beyond*, 37-MAY Champion 12 (2013). Cognitive bias is, of course, not the sole explanation available or offered by scholars to explain *Brady* error. See e.g., Yaroshesky, *supra*.

⁸ Raymond S. Nickerson, *Confirmation Bias: A Ubiquitous Phenomenon in Many Guises*, 2 REVIEW OF GEN. PSYCH. 175, 175 (1998).

⁹ *Id.* at 175 ("It refers usually to unwitting selectivity in the acquisition and use of evidence. The line between deliberate selectivity in the use of evidence and unwitting molding of facts to fit hypotheses or beliefs is a difficult one to draw in practice, but the distinction is meaningful conceptually, and confirmation bias has more to do with the latter than with the former.").

¹⁰ See e.g., Burke, *supra* note 7, at 1603-1613.

through virtual reality (immersive virtual environments), if properly designed and engaged, can effectively modify an individual's explicit and implicit cognitive bias and resulting behavior.¹¹ This article explores whether the innovative power of digital avatars might be harnessed to enable prosecutors to more effectively see the exculpatory nature of evidence and to be more inclined to disclose it. If the power can be harnessed for that purpose, avatars may reinforce or re-introduce prosecutorial self-regulation as a first line of defense against *Brady* violations.

HEALTHCARE'S GORDIAN KNOT: TECHNOLOGICAL INNOVATION AND CLINICAL COSTS

M. Gregg Bloche*

*Georgetown Law

After several years of deceptive stability in the last, deep recession's wake, medical spending has resumed its long-term rise. The central, intractable obstacle to long-term cost containment remains the near-impossibility of saying "no" to ever-more-expensive care that yields small marginal benefits. Psychology, culture, clinical ethics, law, and stakeholders' settled expectations lock in this impossibility. Not surprisingly, regulatory and market-driven strategies urged by both the left and right have failed for decades to surmount it. We propose, instead, to circumvent it, by redirecting cost-control policy away from efforts to limit use of existing, low-benefit technologies and toward strategies for influencing the emergence of new technology. To this end, we urge: (1) redesign of value-based payment to emphasize variable future rewards for tests and treatments that haven't yet emerged, and (2) varying the duration of intellectual-property protection and other market exclusivities so as to tie their rewards to therapeutic effectiveness. Our aim is to transform research and development incentives by more generously rewarding therapeutic breakthroughs while shrinking payoffs for me-too and marginal advances. By reshaping incentives at the R & D stage, before stakeholders make large financial commitments and stoke public expectations, health policy can promote high-value advances while discouraging the marginal innovations that are the main drivers of rising costs.

The strategy we urge was, until recently, impractical. Long lag times between initiation of prospective clinical trials and publication of results, plus narrow patient inclusion criteria, made their "gold-standard" evidence mostly unavailable in "real time," for the purpose of setting payment rates or periods of market exclusivity. But medicine's ongoing big-data revolution, made possible by electronic records and interoperability, is transforming this picture. Comparative efficacy can be tracked in near-real time for large numbers of patients, and suspected confounders can be factored out. Working with an aggregator of such data, from multiple mid-Atlantic health care systems, we are attempting a proof-of-concept for several high-cost cancer therapies.

¹¹ 11 On the use of avatars to reduce cognitive bias generally and with respect to explicit bias toward elderly persons, see e.g., Nick Yee and Jeremy Bailenson, *Walk a Mile in Digital Shoes: The Impact of Embodied Perspective-Taking on Reduction of Negative Stereotyping in Immersive Virtual Environments* (Jan. 2006) (last accessed Jan. 5, 2018) available at <https://www.semanticscholar.org/paper/Walk-A-Mile-in-Digital-Shoes-The-Impact-of-Embodie-Yee-Bailenson/ec4dcaa6cd9841bcc0993cdd365f720ebf9b6f3e>. On the use of avatars to reduce implicit cognitive bias based on race, see e.g., Domna Banakou, Parasuram D. Hanumanth, and Mel Slater, *Virtual Embodiment of White People in a Black Virtual Body Leads to a Sustained Reduction in their Implicit Racial Bias*, 10 FRONTIERS IN HUMAN NEUROSCIENCE 1 (2016) (last accessed Jan. 16, 2018), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5126081/pdf/fnhum-10-00601.pdf>. But see Victoria Groom, Jeremy N. Bailenson, and Clifford Nass, *The influence of racial embodiment on racial bias in immersive virtual environments*, 1 (Psych. Press, 2009), (last accessed Jan. 16, 2018), available at <https://vhil.stanford.edu/mm/2009/groom-racial-embodiment.pdf>. For a discussion of the potential of virtual reality for social neuroscience research, see Thomas D. Parsons, Andrea Gaggioli, and Giuseppe Riva, *Virtual Reality for Research in Social Neuroscience*, 7 BRAIN SCIENCES 42 (2017), (last accessed Jan. 16, 2017), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5406699/>.

GLOBAL PERSPECTIVES ON CONSCIENCE RIGHTS IN HEALTH CARE

Mary Anne Bobinski*

*Allard School of Law, University of British Columbia

Health care professionals have asserted conscience rights in refusing to provide a wide range of health services, information or referrals. These objections may apply to all patients or to the provision of care to specific types of patients, such as the use of reproductive technology by members of the LGBTQ community. The Trump Administration recently created the Conscience and Religious Freedom division in DHHS to highlight protection for these concerns. This talk will explore the issue of conscience rights from a global perspective, focusing on recent developments in conscience rights in Canada, Australia and the U.K. The talk will also consider the influence of the U.S. debate internationally and the relevance of comparative approaches.

ARE UNIVERSITIES PATENT TROLLS OR TARGETS? ANALYZING A DECADE OF UNIVERSITY PATENT LITIGATION

Tania Bubela*, Yael Mansour, Mark Bieber, and Brian Howard

*Simon Fraser University

In 2007, Mark Lemley posed the provocative question – are universities patent trolls? Patent trolls, otherwise known as patent assertion or non-practicing entities (NPEs), which aggressively assert aggregated patent rights. NPEs operate from a position of strength in that they cannot be countersued for infringement because they have no products in a market to threaten and they have no repeat-player constraints. There is speculation that NPEs may have a hold-up impact on innovative sectors, especially information and bio-technology. It is unclear, however, whether universities, as holders of substantial patent portfolios mediated by their technology transfer offices, act as NPEs or may be the target of aggressive litigation. To shed light on this issue, we analysed US patent litigation filings in which a university, research institute or affiliated hospital (collectively university) was a party from 2006-2017, identified in the LexMachina legal analytics database (lexmachina.com). Collectively, universities were plaintiffs in 424 cases and defendants in 84, over 648 patents. There was a spike (3X) in filings in 2013, despite 2011 rule changes under the *America Invents Act* designed to reduce patent litigation. The majority of cases settled. The most common fields were human therapeutics, molecular diagnostics and devices, followed by semiconductors and related devices. In the majority of cases the university was a co-plaintiff/defendant alongside an exclusive licensee, including university spin-off companies, but we provide a summary of litigation between universities (e.g., *Trustees of the University of Pennsylvania v. St. Jude Children's Research Hospital* over cancer immunotherapy CAR-T constructs). Nevertheless, the volume of litigation imposes substantial costs on universities. Universities involved in the most litigation were Boston University (n=43), Stanford University (n=33), and Duke University (n=24). Our results conform with Mark Lemley's conclusion that universities are not acting as patent trolls, however, we are in the process of analyzing whether universities are licensing to NPEs. The volume of litigation may best be addressed through careful consideration of exclusive licensing practices and terms.

LAWYERS' ROLE IN ART CONTRACTS OF UNCERTAIN ENFORCEABILITY

June Carbone*

*University of Minnesota Law School

The talk will address the obligations of lawyers in the context of unregulated surrogacy and other ART transactions. In particular, the talk will consider what obligations lawyers have to clients to inform them of the questionable enforceability of clauses related to abortion, selective reduction and other matters. The talk will address the purpose such clauses serve in establishing parties' expectations and the duty of

lawyers in calling attention to such clauses, especially where clients may be relying on the other party's agreement to clauses that may be unenforceable as a matter of law.

NORMATIVE CONSIDERATIONS ABOUT "IDENTITY" IN NEUROTECHNOLOGY: I, ROBOT?

Bill Casebeer*

***Lockheed Martin**

A review of the literature in theories of personal identity to discuss what impact neurotechnology for memory sharing (such as that being developed by Google's Division Eight) might have on notions of the extended self--I will sketch out tensions between libertarian and communitarian notions of the self that this technology highlights and what upshot this has for our self-conception.

DATA-HOARDING IN GENOMICS CAN KILL. WHAT CAN WE DO ABOUT IT?

Robert Cook-Deegan*

***Arizona State University**

Interpreting the clinical significance of genomic variants that confer risk of disease among the more than 20,000 human genes is a task well beyond the capacity of even the largest labs, medical centers, and even national health systems (where they exist; clearly not in the USA). Making clinical use of genomic data will necessarily entail collecting such data and linking them to clinical, environmental and personal/social data, while following outcomes over time. Sources of genomic data have already shifted from primarily research studies to clinical, ancestry, and other genomic testing in commercial laboratories. The databases, expert curation, and pooling of data are essential, but diaphanous and only somewhat organized. Business incentives are disparate, and some proprietary strategies actively undermine data-pooling. The "community" needed to establish a commons is only beginning to realize the extent of the problems and the need to build infrastructure and develop rules. The talk will progress from some examples of how people are harmed by deficiencies in the current system, point to some possible solutions, and end with suggestions for legal and social science research to address the problems.

EMBRYO MOSAICISM AND IMPACTS ON CLINICAL PRACTICE IN REPRODUCTIVE MEDICINE

Judith Daar*

***UCLA School of Law (visiting); University of California Irvine, School of Medicine**

Advances in preimplantation genetic testing (PGT) of embryos permit prospective parents to learn a great deal about their potential future child's health, including whether the child will experience health impacts caused by aneuploidy - the presence of too many or too few chromosomes in each cell. Now nearing the end of its third decade in use, PGT has grown in sophistication and accuracy which in turn poses challenges in the informed consent arena precisely because of the highly technical data genetic testing reveals. Provider disclosure challenges have intensified over the past several years as PGT laboratories began to report on the phenomenon of embryo mosaicism – a condition in which testing detects more than one cell line in the blastocyst. Typically, a mosaic embryo contains one normal (euploid) cell line and one abnormal (aneuploidy) cell line, making it possible that the resulting child could be born with a health-affecting genetic anomaly. Some estimates place the number of embryos detected as mosaic through PGT as high as 30 percent of all embryos screened.

The main challenge mosaic embryos currently present is that physicians simply do not know if the resulting child will express the normal cell line (healthy) or the abnormal cell line (unhealthy). A handful of studies found that when certain mosaic embryos were transferred into the patient's uterus after full disclosure of the potential outcomes, the resulting babies were born with a normal genome. Researchers speculate that the abnormal cell line migrated to the trophoctoderm (the part of the early embryo that becomes the placenta, not the child), or self-corrected at some point in early embryonic development. While advancing technologies - including high-resolution next-generation sequencing - allow mosaicism to be detected with greater sensitivity than earlier methods, researchers and clinicians remain uncertain about whether any resulting child will be born with a normal genome. Given this uncertainty, the health care team must wrestle with decisions regarding transfer of such embryos as well as the nature and extent of information to be shared with the patient as part of the informed consent process.

This presentation will review the current state-of-the-art in PGT as it relates to embryo mosaicism. Based on recent interviews, the presentation will discuss select clinic practices regarding transfer of embryos deemed mosaic. To aid in further development of best practices under these clinical circumstances, the presentation will suggest the rights and interests a clinic could consider in developing a policy that meets the requirements of informed consent. Whether insisting that no mosaic embryo should be transferred because of its potential to yield an unhealthy child, or agreeing to transfer based on the reproductive autonomy of the patient, fertility clinics are encouraged to act in a consistent manner with constant vigilance to emerging data in the field.

BIOETHICS V BIOPOLITICS

Osagie K. Obasogie* and Marcy Darnovsky†

***University of California, Berkeley, Joint Medical Program and School of Public Health; †Center for Genetics and Society.**

For decades, the field of bioethics has shaped the way we think about ethical problems in science, technology, and medicine. But its traditional emphasis on individual dynamics such as doctor-patient relationships, informed consent, and personal autonomy is minimally helpful in confronting many of the social and political challenges posed by new human biotechnologies such as assisted reproduction, human genetic modification, and DNA forensics.

We argue that these issues, and the legal and policy challenges related to them, can best be understood and addressed from an emerging standpoint that is attentive to race, gender, class, disability, privacy, and notions of democracy—a “new biopolitics.” An anthology that we have edited, which will be released this March (*Beyond Bioethics: Toward a New Biopolitics*, University of California Press), brings together the work of several dozen cutting-edge thinkers from diverse fields of study and public engagement, all of them committed to this new perspective grounded in social justice and public interest values.

At BioLaw LaPalooza we propose to provide a brief but provocative overview of the concerns that motivated the compilation of this volume and that underlie the work of its contributors. We anticipate a lively exchange.

NEUROSCIENCE AND THE PERSONALIZATION OF CRIMINAL LAW

Deborah W. Denno*

***Fordham University School of Law**

How can advances in neuroscience help make the criminal justice system more personalized, effective, and fair? I have gathered an original database of every criminal case that has addressed neuroscience evidence in any capacity over the course of two decades (totaling 800 cases), thus providing a nuanced and multifaceted assessment of how and why neuroscience evidence is actually used in criminal courts and the implications it can have for criminal justice reform.

This proposed talk will focus on how defendants construct personalized defenses in the criminal law, especially those that most readily comport with neuroscience evidence: diminished capacity, insanity, competency, lowered mens rea, or involuntariness. The talk will analyze the nature and extent to which attorneys attempt to personalize their clients by relying on neuroscience and what appear to be the most successful strategies. The talk will also assess how funding impacts on how well attorneys can defend their clients by using neuroscience evidence. If in fact the level of personalization that neuroscience affords can be effective for mitigating sentences—and initial results show it can be—then it is important for the criminal justice system to provide appropriate financial support for defense attorneys to acquire testing for their clients, within reason of course. My (as yet unpublished) research demonstrates that some state systems are more efficient and successful than others by way of ensuring the availability of resources, especially sophisticated tests and testifying experts.

Yet the process of investigating, introducing, and challenging neuroscience evidence within the parameters of a criminal courtroom is costly. Many of the criminal cases in my extensive database include a host of experts for both the prosecution and the defense. Further analysis of my data will enable an evidence-based assessment of the involvement of such experts, with the goal of developing a more fair and cost-efficient system to address the needs of defendants for whom neuroscience evidence is most relevant and incarceration least effective. If, in their earliest interactions, police officers are trained to recognize would-be defendants with potential mental disabilities (and there are now such programs in place), it may be possible to embark upon a path that avoids courtrooms altogether for these individuals.

Neuroscience research will continue to impact how law and society view human nature and human actions. The key question becomes whether the criminal justice system will adapt to the explosion of neuroscientific information through conscious deliberation, what this proposed talk recommends, or through haphazard implementation of discrete decisions—the direction is which our criminal justice system seems to be headed. The answer will determine how fair and effective we want our justice system to be.

MYRIAD IN THE US AND AUSTRALIA

Rochelle Dreyfuss* & Dianne Nicol⁺

***NYU School of Law; ⁺University of Tasmania**

This paper examines the Myriad decisions in the United States and Australia, which bar patents on naturally occurring products—specifically, on isolated genes. These decisions leave many open questions on the patentability of products and processes that duplicate (or come close to duplicating) material found in nature. They release material for free use by researchers and for patient care. However, they also endanger the future of privately-supported research in the life sciences. The two decisions are, however, not identical and their local impact also appears to be considerably different. The paper will explore these differences. First, we will ask whether the Australian decision suggests limiting principles: a path to a patent law that deals more successfully with dual-use technologies (inventions that are simultaneously research inputs and commercial outputs). We are, however, skeptical about that possibility. Second, we look at the factors in Australian practice that ameliorated the effects of gene patenting prior to the decision in Myriad and suggest ways in which US law could better reflect those factors to create greater certainty for all stakeholders.

BRAIN SCIENCE AND THE LAW OF CONSENT: COGNITIVE AND VOLITIONAL CAPACITY

Jennifer A. Drobac*

***Indiana University Robert H. McKinney School of Law**

Based upon Jennifer A. Drobac and Oliver R. Goodenough, The Myth of Consent (contract for publication with Cambridge University Press, anticipated 2019)

This talk will explore why the scientific facts concerning particular adult neurological and psychosocial conditions are incongruent with the civil law of consent. Specifically, it will focus on not only cognitive capacity, but also volitional capacity. It challenges the Milton Friedman notion of the “rational actor” and concepts of “radical consent.” It examines how brain sciences suggest a different approach to an evaluation of adult consent. The book, upon which the talk will be based, is the second monograph of a continuing academic inquiry concerning brain sciences and the civil laws regarding consent, pertinent to a number of adult, as well as juvenile, populations.

The talk will present specific brain science and explore how it demonstrates inconsistencies between human functioning and current civil law regarding consent and capacity.

EVERGREENING IN THE HIGHEST GROSSING DRUG COMPANIES

Robin Feldman*

***UC Hastings College of Law**

Even in sub-optimally competitive markets such as health care, one might expect to see some measure of competition, at least in certain circumstances. Although anecdotal evidence has identified instances of evergreening, which can be defined as artificially extending the protection cliff, we wanted to examine the extent to which the behavior is pervasive. Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry?

This study examines the products of the top 15 highest grossing drug companies between 2005 and 2015, identifying and analyzing every instance in which the companies added new patents or exclusivities. The study draws from a data set we developed encompassing all non-biologic drugs on the market between 2005 and 2015. Assembling the data set involved extracting and interpreting 160,000 individual data points from archival FDA data, much of which is no longer available from the FDA itself. We intend to make the data set public upon publication of our work.

SPERM DONATION ERRORS AND RACE

Dov Fox*

***University of San Diego School of Law**

As a lesbian growing up in a small farm town, Jennifer Cramblett knew the sting of not fitting in. When she and her partner decided to start a family, they looked for a donor who'd resemble them. But the sperm bank switched the white donor she'd requested with a black one. Their “obviously mixed race[] baby girl” marked them as racially different in their 98%-white suburb. Their daughter's “irrepressibl[y]” African-American heritage disrupted the couple's vision of the normalizing family life they'd hoped for. The mix-up forced them to face her community's indifference to racial exclusion and the stinging insults of an uncle who “speaks openly and derisively about persons of color.” Cramblett's pending federal diversity suit complains that she lacks the “cultural competency” required to navigate the unplanned “challenges [of] transracial parenting.”

My project argues that the harms Cramblett suffered, real though they are, should find no recourse under the law. Judicial recognition of those injuries, framed as a response to racial prejudice and disadvantage, would dignify the very biases to which the Supreme Court has in the child-custody context declared “the law cannot, directly or indirectly, give [] effect.” Reproductive autonomy and wellbeing warrant robust legal protection. And race sorting in family formation remains a source of evolving conflict more than anything approach consensus. But courts would err to wield the power of the torts system to breath life into the divisive message that it is worse for prospective parents to have children with darker skin or mixed ancestry.

EXPLORING SOME LEGAL IMPLICATIONS OF NEUROSCIENCE RESEARCH FINDING SEX DIFFERENCES IN THE BRAIN

Betsy Grey*

***Sandra Day O'Connor College of Law, Arizona State University**

Research in neuroscience increasingly is documenting real (if not earth-shattering) differences between male and female brains, including structural, maturation and hormonal differences. Research also observes sex-associated differences in cognition and behavior, including sex-biased conditions of mental disorders. For a long time, the neuroscience community mostly considered any observed sex-associated differences in cognition and behavior in humans to be due to the effects of cultural differences. But now scientists are beginning to ask whether brain differences may contribute to those differences.

Given this research, will law need to take into account sex-biased differences in cognition and behavior? Should it ignore those differences or accommodate them? Discrimination law, for example, has (appropriately) been hostile to differential treatment based on sex. Should advances in neuroscience create room for any exceptions to the societal values of equal treatment?

This project is at its earliest stages. In the talk, I will give some examples of legal doctrine and theory that may be challenged by these neuroscience advances and invite feedback in ways to approach them.

TECHNOLOGY, PATIENTS, AND THE LAW

Leslie C. Griffin* & Paul Harlan Janda

***University of Nevada, Las Vegas, William S. Boyd School of Law**

Dr. Paul Janda is a neurologist at the Las Vegas Neurology Center. He is also Program Director of the Neurology Residency Program at Valley Hospital Medical Center. And a Californian by birth from two California doctors! He attended both Stanford and Berkeley undergrad, and has an impressive list of medical credentials, including time at Touro, UCLA, and Wake Forest. He is also a 2016 graduate of the law school where I teach, UNLV. He is now the first and only board certified neurologist-lawyer in Nevada. Janda helped to write and pass a recent Nevada brain death statute that uses the American Academy of Neurology's evidence-based standards to set uniform legal guidelines for the determination of brain death.

Janda was never my doctor or my student. But he spent time in the hospital where I was recovering from a brain injury. He gave encouragement and advice to my family, friends, and colleagues, who were all there simply waiting for me to wake up.

Unfortunately, Dr. Janda's work schedule makes him unable to attend this conference. He has agreed to write, with me, an article about brain injury and technology. I will present the talk and we will write it.

I have two slides to show you. The first is an MRI of my brain in April 1993. I had just graduated from law school in 1992 and was clerking for Ninth Circuit Judge Mary Schroeder in Phoenix. Several weeks earlier I had won a prestigious research fellowship to Harvard. Then a car hit me as I was crossing the street. Janda says this was a serious injury but it looked like I received good surgical care.

The second picture is more recent. On October 7, 2016, a stranger attacked me, picking me up, throwing me on my head, and then kicking me. He was imprisoned to 6-15 years for attempted murder.

In my experience, the first injury was much worse than the second. However, according to Dr. Janda, this second slide, with its blood within the brain, was "more threatening" than the first.

Both times some of my doctors predicted either my death or my permanent confinement with serious brain damage. Dr. Janda admits he has never seen anyone recover as I did from such a serious injury.

After such an experience, there are lessons to be learned and work to be done. This paper will focus on the relationship among technology, patients, and the law.

Technological improvements were part of Dr. Janda's work in the brain death area, for example, when he helped to change the law to set uniform medical guidelines for death. His work for this paper will explain

the technological details of recognizing brain injuries in general and my two injuries in particular. He will focus on the best ways doctors can use technology to serve health.

I will tell my patient's story. I can identify ways that patients are harmed by the type of treatment we currently receive. The patient's road is much more difficult than it appears to outsiders, and needs much improvement. I then recommend methods that should be devoted to our care.

We then identify how the law can improve the use of technology and increase patient care in the brain injury area.

THE STRUGGLE FOR ACCESS TO MEDICAL MARIJUANA IN HISTORICAL PERSPECTIVE

Lewis A. Grossman*

***American University Washington College of Law**

I would like to discuss following chapter from my book-in-progress titled *Choose Your Medicine: Freedom of Therapeutic Choice in American History and Law*.

Chapter Eight—Life, Liberty, [and the Pursuit of Happiness]: The Struggle for Access to Medical Marijuana in Historical Perspective

The struggle for access to medical marijuana differs from other battles for therapeutic freedom described in this book because marijuana also has a popular, though controversial, nontherapeutic use—delivery of a recreational high. This distinctive characteristic of cannabis has posed special legal, political, and rhetorical challenges for medical marijuana advocates.

First, many citizens, judges, and government officials oppose the legalization of marijuana for medical uses, regardless of whether it offers actual therapeutic benefits. They do so because of the public health harms and moral degradation they associate with drug abuse. These opponents suspect (with good reason) that many “medical marijuana” purchasers are actually recreational users. Moreover, they fear (again with good reason) that many pot activists consider medical cannabis legalization to be simply the first step on the path to full legalization.

A second unique problem for medical marijuana advocates is that the Drug Enforcement Administration, likely for political reasons, continues to categorize marijuana as a Schedule I controlled substance—that is, one with “no currently accepted medical use” and a “high potential for abuse.” Consequently, researchers interested in assessing marijuana’s therapeutic efficacy confront high, and often insurmountable, regulatory obstacles.

A third, less obvious problem for medical marijuana supporters—reflected in the slogan “Health before Happy Hour”—has been negotiating their strained affiliation with advocates for comprehensive marijuana legalization. Medical marijuana proponents have long contended that the broader legalization drive neglects the critical needs of patients by accepting regulatory conditions unacceptable to medical users. These conditions include, for example, limits on product strength and amount and the imposition of sales or sin taxes. Conversely, supporters of recreational use believe, accurately, that medical marijuana proponents are often ambivalent about comprehensive legalization and sometimes work to obstruct it.

Following an introduction, this chapter considers regulation of the medical use of alcohol during prohibition as a historical and legal precedent. It then highlights the issues mentioned above while relating the story of the medical marijuana movement from the 1970s to present. This campaign is one of the prime examples of a successful extrajudicial social movement for liberty of therapeutic choice. As late as the 1990s, less than 30 percent of Americas supported the legalization of medical cannabis; today nearly 90 percent do. Although courts have uniformly rejected arguments for medical marijuana access, therapeutic use of the drug is now legal in the majority of states.

Nevertheless, medical marijuana advocates face new challenges. Unless Congress extends a law preventing federal interference with state medical marijuana programs, Attorney General Jeff Sessions—who has officially rescinded the hands-off enforcement approach set forth in the Obama-era “Cole Memorandum”—seems prepared to resume prosecutions. Conversely, if this or a subsequent administration permits the small but growing number of states that have legalized recreational use as well

as medical use to implement these policies, medical cannabis risks losing its distinctiveness, both as a commercial market and as a focus of activism.

FOLLOW-ON BIOLOGICS ARE SET UP TO FAIL

Yaniv Heled*

*** Georgia State University College of Law**

In their article, “Biologics: The New Antitrust Frontier,”¹ Michael Carrier and Carl Minniti provide a comprehensive review of the various kinds of antitrust violations that beleaguer pharmaceutical markets in the United States. Carrier & Minniti examine the applicability of these anticompetitive behaviors to biopharmaceutical (a.k.a. biologics) markets, and in doing so alert regulators and courts to such potential antitrust violations in the emerging area of follow-on biologics. Carrier & Minniti’s article also provides recommendations for limiting anticompetitive behavior in biologics markets that will, no doubt, serve as a valuable guide for regulators, judges, and practitioners. Yet, Carrier & Minniti’s article appears to share in an optimism about the prospects of such markets: that if we just policed them properly, competition could be guaranteed and, with it, prices would drop significantly. Such optimism is unwarranted.

The legislative and regulatory efforts to instill competition into biologics markets have been fraught, from their outset, with persistent and mostly successful counter-efforts by the brand-name pharmaceutical industry (“Industry”) to make follow-on biologics a limited and contained regulatory and commercial phenomenon. To that end, the Industry—with its lobbying spearheads, BIO and PhRMA—and its many allies in Congress, state legislatures, and state and federal administrations, have been waging war to maintain existing and erect new regulatory obstacles to the development, approval, and marketing of follow-on biologics. The Industry’s success in undercutting the emergence of truly competitive follow-on biologics markets thus far rests on four pillars: (1) an Industry-favorable, obstructed pathway for the approval of follow-on biologics; (2) acceptance and upholding of the view that regulatory filings submitted to the FDA are proprietary and confidential; (3) state laws making onerous the substitution of biologics with follow-on versions thereof; and (4) efforts to block any and all specific attempts to make, gain approval for, and sell follow-on biologics. Of these four pillars, the area of antitrust law (and, thus, Carrier & Minniti’s article) addresses mostly the fourth. Yet, the emergence of competitively robust follow-on biologics markets requires dismantling more than one pillar. Until then, efforts to open biologics markets to competition will continue to be no more than a rearguard battle over the approval and marketing of a small number of follow-on versions of a mere handful of original products with limited substitutability. The price, as always, will be borne by payors, patients, and ultimately, the public.

In this comment, I discuss each of the four pillars supporting the Industry’s success in inhibiting the development, approval, and marketing of follow-on biologics. I show that unlike the story of the Hatch-Waxman Act, that of the Biologics Price Competition and Innovation Act (BPCIA) does not and probably will not have a happy ending; that if the goal is to significantly lower biologics’ prices, then the paradigm of approval of follow-on biologics in the United States would need to change.

THE EFFECTS OF AGE AND GENDER ON THIRD-PARTY PUNISHMENT

Morris Hoffman*, Francis Shen, Vijeth Iyengar, Nina Motazed, & Frank Krueger

***Second Judicial District, State of Colorado**

Do humans punish norm violators more harshly or less harshly as we age? This question is not only important in its own right, as researchers begin to study third-party punishment in a systematic and interdisciplinary fashion, but it also bears on vital public policy issues, including what sorts of individuals we

¹ Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 Ill. L. Rev. 1 (2018).

should be selecting as our judges and jurors. Using well-studied criminal hypotheticals, which varied both the level of harm and the wrongdoer's mental state (whether he was acting intentionally or just recklessly), our experiment showed there are significant interaction effects between the punisher's age and gender, and the level of harm caused by the norm violation, in both the intentional and reckless conditions. Older men punish low-harm violations much less harshly than younger men, but this difference reverses when the harms become high—older men punish high harms more harshly than younger men. Women punishers did not exhibit this age-inversion phenomenon, but did punish more harshly than their same-age male counterparts across all harms. These patterns persisted when we analyzed data from the World Values Survey. To confirm their ecological validity, we are also surveying several hundred actual criminal cases from the state of Colorado decided between 2001 and 2016.

FOR MONOCLONAL ANTIBODIES, COMPLIANCE WITH THE WRITTEN DESCRIPTION REQUIREMENT HAS BECOME A MOVING TARGET

Christopher M. Holman*

***University of Missouri-Kansas City Law School**

Monoclonal antibodies (Mabs) form the basis for some of the most important products of biotechnology. In 2016, for example, six of the top eight blockbuster drugs were based on monoclonal antibodies, with AbbVie's Humira (adalimumab) leading the pack with reported revenues exceeding \$16 billion. Given the increasingly high cost of bringing new drugs to the market, and the abbreviated approval processes available to competitors under the Biologics Price Competition & Innovation Act (BPCIA), effective patent protection for monoclonal antibodies will continue to be an important consideration in a company's decision to develop new monoclonal antibody-based products. Until fairly recently, U.S. patent law seemed to offer relatively robust protection for monoclonal antibodies. In particular, rulings of the Court of Appeals of the Federal Circuit in 2002 and 2004 interpreted the patent law's written description requirement in a manner that purported to sanction patent claims broadly reciting a genus of functionally defined antibodies. However, in 2011, 2014, and now again in October, 2017, the Federal Circuit has issued opinions that disavow and effectively overrule the court's earlier, patentee-friendly decisions, and which appear, at least for the time being, to have established the written description requirement as a major limitation on the available scope of patent protection for monoclonal antibody-based technologies. My paper will trace the history of the *Lilly* written description requirement (LWD) as applied to antibodies, beginning with a series of PTO guidelines and training materials (the "Guidelines") that were issued in the wake of the Federal Circuit's landmark *UC Regents v. Eli Lilly* decision in 1997, and then turning to five Federal Circuit decisions that have interpreted antibody-specific provisions of the Guidelines and/or applied the LWD to monoclonal antibody claims, including the court's most recent decision in this area, *Amgen v. Sanofi* (2017). It will then provide analysis, commentary, and suggestions for moving forward.

FOR BETTER OR WORSE: THE FDA'S ROLE IN REGULATING PHARMACEUTICAL IMPROVEMENTS

Dmitry Karshedt*

***George Washington University Law School**

Pharmaceutical companies have recently faced antitrust liability for introducing into the stream of commerce modified versions of drugs that they currently market—an activity that, on the surface, appears at worst benign and perhaps even salutary. Nonetheless, litigation has revealed that these companies sometimes change compositions of their drug products not because new formulations would lead to improved health outcomes, but principally in order to execute a strategy for effectively extending exclusive rights to sell their drug products by substituting the patented drug modifications for pioneering versions that are going off-patent. This strategy runs counter to the goal of the legislative framework regulating branded and generic

drug approvals, which was to provide incentives for discoveries that raise the quality of patient care and human health by means of appropriate periods of exclusivity for manufacturers of branded drugs.

In this Article, I contend that the ways in which extant rules of patent law apply to drug inventions, certain features of the regulatory framework under the federal Food Drug, and Cosmetic Act and its interactions with so-called “generic substitution” under state laws, and unique market forces in the pharmaceutical sector may combine to subvert the goal of the brand-generic framework, and propose a regulatory correction. I explain that the Food and Drug Administration (FDA) is well-positioned to induce the generation of useful comparative data that would help increase transparency with respect to drug modifications and propose a novel legal framework for rewarding firms that generate such data. I argue that this framework would discourage pretextual drug changes by pharmaceutical manufactures and thereby limit attempts to achieve questionable exclusivity extensions, help market participants identify such approaches when they are undertaken, and improve patient care and promote downstream clinical research based on scientific evidence gathered under the directives of the proposed scheme. Indeed, the FDA-focused solution advanced in this Article would help ensure that firms that actually focus on improving their pioneering drugs would receive both regulatory and market rewards, while firms that do not would continue to be exposed to litigation and face unfavorable treatment of their products from payers and physicians.

MEDICALIZATION AND THE NEW CIVIL RIGHTS

Craig Konnoth*

***University of Colorado Law School**

For decades, minority groups such as African-Americans, women, gays, and people with disabilities, have long looked to the law for protection. Their group identities would incorporate a narrative based on a quest for legal rights, of legitimacy, and of vulnerability. Law helped raise consciousness and consolidate identity around a cause. Judges would acquiesce in these discourses, rendering law into, what I term, a civil rights discourse.

Even as the heyday of minority rights-seeking through judicial intervention retreats, many individuals and groups seek rights, not through legal, but rather, through medical frames. Medicine, even today, is viewed suspiciously by the vast majority of progressive scholars and activists as a tool of surveillance and social categorization, control, intervention, and coercion. This Article argues, however, that as in the case of the law, groups constitute their identities using medical categories. These medical categories help them understand how their bodies function, and help situate them within certain spaces in medical and other institutions. Through these spaces, they build consciousness that coalesces into rights seeking goals. Medical discourse is deployed to seek goals both for treatment and management of their condition, but also as part of a broader movement to change society's attitudes and treatment of various groups.

Medical discourse is buttressed by certain legitimacy claims that evolved over the last century. From being considered the fault of the individual, who could seek charity, but nothing more, technological discoveries transformed the perception of medical conditions into no-fault occurrences. Individuals had a valid claim on society to address those claims. This rationale undergirded the period's rehabilitation and social security enactments. Later in the century, by comparing themselves to racial minorities, those invoking medical discourse adopted a social constructivist position. The harms those with medical conditions faced arose from society's attitudes and structures. Legislation like the Americans with Disabilities Act reflects this position.

From these legitimacy narratives spring gatekeeping approaches. Disputes arose over which conditions were truly “medical” in nature. And only those medical conditions which are seen as not the fault of the individual (usually immutable conditions), and which do not invite social maltreatment (visible conditions, and those that deny individual social interaction and access to jobs) obtain the most protection. In so doing, law largely delegates the rights-producing function it once monopolized to medicine; medicine is infused with rights discourse, transforming in important ways the relationship between medicine and the law.

LEGITIMATE MEDICINE IN THE AGE OF CONSUMERISM

Matt Lamkin*

***The University of Tulsa College of Law**

What is a “legitimate medical purpose” for prescribing drugs? Under federal law, prescribing medications without such a purpose renders a physician a “drug trafficker” subject to draconian penalties. Yet the DEA and courts have steadfastly refused to specify which purposes qualify as legitimate, even as they condemn to prison physicians who run afoul of this requirement. Instead, drug enforcement actors have alternated between insisting, on the one hand, that the phrase “legitimate medical purpose” is impossible to define with any particularity and, on the other, that its meaning is so obvious that no elaboration is necessary.

Recent developments highlight the growing importance of clarifying the scope of legitimate medicine. In the midst of the opioid epidemic, drug enforcement actors have failed to give physicians sufficient guidance regarding the conduct that runs afoul of the Controlled Substances Act. Meanwhile the increasingly likely prospect of “recreational” drugs like cannabis and MDMA obtaining FDA approval to treat specific conditions raises questions about which off-label prescriptions of these drugs would be deemed to lack a legitimate purpose. If, for example, it would not be legitimate to prescribe cannabis simply to help a stressed-out patient relax, how could this be distinguished from the commonplace prescribing of drugs like Xanax to help healthy patients cope with sub-diagnostic levels of anxiety? If it would not be legitimate to prescribe cannabis to enhance a patient’s sexual desire, how could this prohibition be reconciled with the FDA’s recent approval of another drug for precisely this purpose?

On the sole occasion when the federal government has been pressed to define the scope of legitimate medical practice with particularity (in *Gonzales v. Oregon*), the government argued that “legitimate” medicine encompasses only those interventions that “aim to preserve the patient’s health or to cure, alleviate, prevent, or ‘treat’ the disease or its symptoms in the patient.” Yet merely a moment’s reflection shows medicine’s scope cannot be so narrowly defined. Since the dawn of the Western tradition, medicine has always included practices that are not aimed at healing. Hippocratic doctors prescribed remedies for the purpose of preventing or terminating undesired pregnancies, irrespective of whether women’s health was at risk. Today, physicians routinely offer interventions without any pretense of promoting health – prescribing Botox to enhance physical appearance, benzodiazepines to cope with ordinary social stresses, or (in some states) lethal drug cocktails to hasten death in terminally ill patients.

Medicine’s aims cannot be limited to a narrow set of purposes – at least not without radically redefining the scope of the enterprise. Rather, what distinguishes “medical” practices from other kinds of interventions is not the *ends* being pursued, but the *means* being used to achieve them. Medicine is better understood as the application of certain types of interventions – in particular, technologies rooted in biology and biochemistry – to promote patients’ well-being, broadly conceived. This includes treating and preventing illnesses, but can also include enhancing social and cognitive functioning and improving the well-being of people whose challenges do not rise to the level of disorders.

Understanding medicine as the use of biological interventions to promote patient well-being would not require abandoning efforts to police doctors’ prescribing powers or to mitigate the harms of drug abuse. Instead it would open the door to new ways to regulate drug use and provide clarity regarding the kinds of physician conduct that violate drug trafficking laws.

INJECTING DOUBT: RESPONDING TO THE NATUROPATHIC ANTI-VACCINATION RHETORIC

Timothy Caulfield, Alessandro R. Marcon*, & Blake Murdoch

***University of Alberta**

There is growing controversy about vaccination rates in Canada. A significant percentage of the population is uncertain about the science of vaccines, and in some areas ‘herd immunity’ is being threatened. Hesitancy to vaccinate is a complex phenomenon, but there is little doubt that complementary and

alternative medicine (CAM) providers have played a role. In this study, our first objective was to examine websites of naturopathic clinics and practitioners in the provinces of British Columbia and Alberta, looking for (1) the presence of discourse that may contribute to vaccine hesitancy, and (2) recommendations for 'alternatives' to vaccines or flu shots. Of the 330 naturopath websites we analysed, 40 included vaccine hesitancy discourse and 26 offered vaccine or flu shot alternatives. Using these data, we explored the potential impact such statements could have on the phenomenon of vaccine hesitancy. Our second objective was to consider these misrepresentations in the context of Canadian law and policy, and to outline various legal methods of addressing them. We concluded that tightening advertising law, reducing CAM practitioners' ability to self-regulate, and improving enforcement of existing common and criminal law standards would help limit naturopaths' ability to spread inaccurate and science-free anti-vaccination and vaccine-hesitant perspectives.

THE ROAD NOT TAKEN: SYNTHETIC BIOLOGISTS AND THE IDEA OF SELF-GOVERNANCE.

Stephen Maurer*

***Goldman School of Public Policy, University of California, Berkeley**

In the early 2000s most synthetic biologists were confident that their community would develop strong private institutions and rules to manage the danger of biological weapons. This paper describes the main initiatives – some successful – that academic and commercial biologists organized to achieve this ambition. It then asks what these experiences say about the prospect for more ambitious initiatives going forward. I close by asking what courts and policymakers can do to promote self-governance, focusing in particular on when self-governance should be permissible under the Sherman Act.

FAIR DATA SHARING & DATA CARING IN THE DIGITALIZED ERA: ASPIRATIONS, REALITIES & LEGAL CLASHES IN THE HEALTH & LIFE SCIENCES

Timo Minssen*

***University of Copenhagen**

The huge prospects of Big Data, advanced machine learning and AI, as well as the shift to more “personalized”, “open” and “transparent” innovation models stress the importance of an effective governance, regulation and stimulation of shareable data-applications in the health & life sciences. Yet, cutting edge medical innovation requires more than freely available big data and machine-generated data. Pushing the boundaries of biomedical research also demands smart data and high quality data that are created and nourished through human intervention and considerable investments in an highly competitive environment. Intellectual Property Rights (IPRs) and related rights come into play when data producers protect their investment in such data. While the need of recalibrating IPRs to fully support “big and smart data” advances is being intensely debated, there seems to be much confusion about the availability of IPRs and their legal effects. This presentation provides a very brief overview on selected areas that demonstrate emerging tensions at the interface of Big Data, Standardization, IPRs and Competition/Antitrust Law.

REFOCUSING ON THE PREGNANT WOMAN IN MATERNAL-FETAL SURGERY: LEGAL AND ETHICAL ISSUES

Seema Mohapatra*

*Barry University Dwayne O. Andreas School of Law

In September 2017, a woman agreed to undergo invasive, experimental surgery in an attempt to to lessen the physical effects of spina bifida in the fetus she was carrying.¹ In this “open” surgery, the surgeon made an incision in her abdomen and lifted out her uterus to operate of her fetus. Her son was born in January, and early reports appear to show that the surgery was successful. Since spina bifida is not a fatal condition, the usual practice was to operate at birth, but the results for postnatal surgery were mixed, with some children were still unable to walk.² In the case of so-called “fetal surgery” (the misnomer most newspapers used when reporting on this recent case, ignoring the pregnant woman), a physician can attempt to fix the defect before birth and prevent damage to the spinal cord from the amniotic fluid.³ Currently, the ideal time for the surgery is from 24-26 weeks of pregnancy.⁴

This Article will survey the maternal-fetal surgery literature from the perspective of the pregnant woman and discuss the emerging legal and ethical issues it raises. Although fetal surgery has been around for over thirty years,⁵ the science is progressing rapidly. It is probable that maternal-fetal surgery will be attempted at earlier points in the pregnancy, pre-viability. This presents a potential issue in terms of a woman’s right to terminate her pregnancy, as well as the physician’s duty towards the woman and the fetus. This raises issues about a woman’s autonomy in decision making and the role of the physician in these interactions. Additionally, as these are experimental procedures, this Article will explore how these studies are structured (with control groups) and which women are offered (or not offered) these potential surgeries.

DECEPTIVELY COMPLICATED

Jane Campbell Moriarty*

*Duquesne University School of Law

This abstract is from a chapter of my book, Are You Lying Now? Neurotechnology and Law (NYU Press, forthcoming 2019).

The interest in neuroscience lie detection is a new phase of an abiding fascination with both deception and the ability to detect lies. The legal system, naturally, has long struggled to determine when individuals are telling the truth—at various times relying upon ordeals, torture, oaths, tests, examinations, and occasionally polygraph. We now rely on judges and jurors to determine the credibility of witnesses but there is much concern that factfinders can be fooled by clever liars.

While most of us believe we are essentially honest and value honesty as a virtue, research in various fields indicates that most humans lie frequently, spontaneously, and often unconsciously. Learning to deceive is part of childhood development and only those with neurodevelopment disorders do not develop this ability. Humans lie about important matters, generally deny that they are deceptive, and engage in self-deception.

¹ Denise Grady, *To Mend a Birth Defect, Surgeons Operate on the Patient Within the Patient*, THE NEW YORK TIMES, Oct. 23, 2017, <https://www.nytimes.com/2017/10/23/health/fetal-surgery-spina-bifida.html?action=click&contentCollection=Health&module=RelatedCoverage®ion=Marginalia&pgtype=article>.

² Denise Grady, *To Mend a Birth Defect, Surgeons Operate on the Patient Within the Patient*, THE NEW YORK TIMES, Oct. 23, 2017, <https://www.nytimes.com/2017/10/23/health/fetal-surgery-spina-bifida.html?action=click&contentCollection=Health&module=RelatedCoverage®ion=Marginalia&pgtype=article>.

³ Denise Grady, *To Mend a Birth Defect, Surgeons Operate on the Patient Within the Patient*, THE NEW YORK TIMES, Oct. 23, 2017, <https://www.nytimes.com/2017/10/23/health/fetal-surgery-spina-bifida.html?action=click&contentCollection=Health&module=RelatedCoverage®ion=Marginalia&pgtype=article>.

⁴ Denise Grady, *To Mend a Birth Defect, Surgeons Operate on the Patient Within the Patient*, THE NEW YORK TIMES, Oct. 23, 2017, <https://www.nytimes.com/2017/10/23/health/fetal-surgery-spina-bifida.html?action=click&contentCollection=Health&module=RelatedCoverage®ion=Marginalia&pgtype=article>.

⁵ Anna Smajdor, *Ethical Challenges in Fetal Surgery*, 37 J. MED. ETHICS 88, 88 (2010).

Although we fear our own deception will be revealed, we experience rage upon discovering we've been lied to.

Why are we so interested in deception and lie detection? Drawing on evolutionary psychology, I will address whether deception is an essential human trait and whether the ability to detect deception successfully may be an evolutionary master key.

CAN WE READ YOUR MIND YET? A CRITICAL REPORT ON THE CURRENT STATUS OF MEMORY DETECTION

Emily R.D. Murphy* & Jesse Rissman

***UC Hastings College of the Law**

Although brain-based memory detection techniques have been used for forensic purposes by police and prosecutors in some countries, such as India and Singapore, efforts to promote their more widespread adoption have quite appropriately been met with hesitation, given uncertainty about their efficacy and reliability. Scientific publications from the past few years report significant advances in empirical evaluations of various aspects of memory detection. These studies use a range of methodological approaches including fMRI with multi-voxel pattern analysis, EEG, and purely behavioral methods such as the relatively novel autobiographical Implicit Association Test. Some of this recent work in memory detection has specifically addressed forensically-relevant factors such as the use of real-world acquired memories, classification of individuals rather than observation of group differences, and the effect of deployment of evasive countermeasures. Moreover, recent publications attempt to independently replicate and verify significant findings, lending additional support to the validity of replicated results. In light of advances in the field, the time is right for a comprehensive critical appraisal of what these studies tell us about the nature of human memory and the viability of memory detection— whether via behavioral or brain-based measures—as a forensic tool, and what outstanding issues remain to be addressed.

REFLECTIONS ON TEACHING A LAW AND NEUROSCIENCE COURSE

Roland Nadler*

***University of Ottawa Centre for Health Law, Policy and Ethics**

Particularly with the advent of the casebook by Jones, Schall, and Shen, professors at law schools and elsewhere are increasingly offering classes on issues at the intersection of law and neuroscience. During the intensive three-week January term at the University of Ottawa, I taught one such course, in a seminar format, to 22 students. My hope is that the experience recounted here yields insights both pedagogical and topical.

Among other highlights, I note: law and neuroscience already offers such a broad menu of weighty topics that any reasonable syllabus will necessarily contain some surprising subject-matter omission or another. Another observation is that despite efforts to keep things doctrinally grounded, discussion of these issues naturally tends toward big-picture legal and philosophical themes. In particular, nearly every session touched on challenging, fundamental questions about how to balance democracy and technocracy / epistocracy in designing the legal system.

A final impression concerns the special nature of the brain as contrasted with other sites of legally-relevant science and technology: I found that to the extent neuroscience is useful in fostering thoughtful examination of law and society, the difference it offers from other varieties of science fiction and science fact seems — surprisingly — more like a difference of degree than a difference of kind. My perception in that regard challenged my own views — not about the importance of neurolaw, but about the *uniqueness* of its importance.

ABORTION LAW FOR 21ST CENTURY DOCTORS

Michelle Oberman*

*Santa Clara University School of Law

In January, 2018, the American College of Obstetrics and Gynecology issued a position statement opposing the punishment of women for self-induced abortion.¹ To those unfamiliar with emerging trends in abortion in the US and worldwide, the need for the declaration might not be apparent. Several studies suggest that self-induced abortion is on the rise here in the US.² A second trend reveals a rise in the prosecution of pregnant women for behavior thought to harm the fetus. The ACOG statement responds to both trends by urging doctors to honor the integrity and confidentiality inherent in the doctor-patient relationship. Seen in the context of the battle over legal abortion, though, the statement has far broader implications. This paper discusses international trends in abortion, legal and illegal, and considers how these trends will affect US doctors.

REGULATING PREDICTIVE ALGORITHMS IN OMIC ASSAYS

Pilar N. Ossorio*

*University of Wisconsin Law School and the Morgridge Institute for Research

Precision medicine will depend on many types of omic assays to help tailor treatments to individual patients. Such assays are already helping health care providers to predict a person's drug responses, characterize tumors by their metabolic pathways or gene expression, and better diagnose autoimmune and rare diseases. Complex computational algorithms, including machine learning algorithms, are increasingly involved in the operation of omic assays and the analysis of assay results. While many omic assays have been offered as laboratory developed tests (LDTs), some have been regulated by the FDA as *in vitro* diagnostics (IVDs) and more may be in the future. A leading cancer genome analytics company, Foundation Medicine, recently received FDA approval (PMA) for its tumor profiling system, the core of which is Foundation Medicine's algorithm (or algorithms). The system, now branded as FoundationOne CDx, was approved as a companion diagnostic for a variety of chemotherapeutic drugs that treat solid tumors of the lung, breast, ovaries, and colon.

The FDA has long regulated medical software, usually as a component of a medical device but the agency will also regulate stand-alone software that meets the regulatory definition of a medical device. The agency regulates devices based on their level of risk, and their level of risk is determined by their intended use. Intended use is determined by evaluating objective indicia of the manufacturer's intent. The manner in which clinicians actually use a device is not evidence of the manufacturer's intent. Nonetheless, I argue that the agency ought to consider how and whether a device would likely be misused because misuse could compromise patient safety and the potential for misuse ought to be considered when classifying a device.

Here, I will describe the results of a pilot study to elucidate and compare the views of medical algorithm developers and clinical oncologists regarding the meaning, strengths, and limitations of assay results produced by complex computational algorithms. Using ethnographic interviews our research team assessed each group's views on what clinicians should know about a test, including its algorithms; what testing should occur before an algorithm-driven assay is introduced into clinical use in oncology; what limitations different types of algorithms introduce into clinical testing; and related questions. We have identified some areas of concordance and discordance between algorithm developers and clinicians, and we identified information about how clinicians understand and use tests that ought to be relevant to the FDA. Our data highlight some technical aspects of algorithm development the FDA might consider when

¹ <https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Decriminalization-of-Self-Induced-Abortion>

² https://www.nytimes.com/2016/03/06/opinion/sunday/the-return-of-the-diy-abortion.html?_r=0; Grossman D, White K, Hopkins K, Potter JE. The public health threat of anti-abortion legislation. *Contraception* 2014;89:73-4.

classifying algorithm-driven assays or authorizing their marketing. The data further point to topics on which the agency should provide guidance. Proper guidance could help algorithm developers produce assays with a lower likelihood of misuse. Assays that comport with clinician expectations are less likely to be misused or misinterpreted. The FDA does not directly regulate the practice of medicine but it can regulate medical device developers in ways that promote safer medical practice.

HOW DO PATENT INCENTIVES AFFECT UNIVERSITY RESEARCHERS?

Lisa Larrimore Ouellette* & Andrew Tutt

***Stanford Law School**

Universities and other beneficiaries of public funding for scientific research are encouraged to patent resulting inventions under the Bayh–Dole Act. This controversial framework gives academic grant recipients a direct financial stake in the success of their inventions by requiring universities to share the resulting patent royalties with inventors. This incentive for grant recipients might help justify Bayh–Dole patents when the conventional justification for exclusivity—that it is necessary for commercialization—fails to hold. But there is little evidence as to whether it works. This Article examines how one aspect of the patent incentive—the prospect of royalties—affects the behavior of university researchers.

Fortuitously, different universities offer inventors different shares of patent revenue. We have created a dataset of royalty-sharing policies from 152 universities, which shows substantial variation across universities and time. (For example, Caltech switched from sharing 15% to 25% of net income in 1994, the University of Washington switched from sharing 100% of initial revenues to a flat rate of 33% in 2004, and the University of Iowa switched from 25% to 100% of initial patent revenues in 2005.) Although prior work has suggested that higher royalties for faculty scientists lead to greater licensing income, we do not observe this effect in our dataset. We also do not see a significant positive impact of higher faculty shares on invention disclosures, patent applications, or issued patents. Additionally, we examined lateral moves by the most active patenters between universities, and we did not find that they were more likely to move to universities offering higher royalty shares.

These results do not imply that patents provide no incentives to university researchers; they may provide reputational benefits or encourage faculty-run spin-offs, or even provide financial incentives that are not captured by our statistics. But the lack of a strong impact of higher royalty shares on the behavior one would expect to be most affected—creation of more and more valuable patents—suggests that, from a social welfare perspective, it may be preferable for a larger share of royalties to be retained by universities, which are then required by Bayh–Dole to reinvest this money in science research and education. In any event, our analysis raises promising questions for future research and calls into question the existing view that increasing the inventor's share in university patent policies encourages researchers to develop and commercialize more remunerative patents.

WHOLE EXOME SEQUENCING IN THE MILITARY HEALTH SYSTEM: LEGAL AND ETHICAL ISSUES

Maxwell J. Mehlman, Efthimios Parasidis*, Mauricio De Castro, Cubby Gardner, Megan D. Maxwell, Amy McGuire, & Robert C. Green

***The Ohio State University Moritz College of Law and the College of Public Health**

The MilSeq Project is a pilot study exploring the implementation of personalized medicine into the United States Air Force (USAF) through whole exome sequencing in apparently healthy, active-duty Airmen. Drawing on study design and implementation of the MilSeq Project, the proposed presentation will examine legal and ethical issues surrounding whole exome sequencing in the military health system. Topics include solicitation of research participants, informed consent, privacy and confidentiality, and how to assess, disclose, and manage the potential for adverse career impact.

Disclaimers

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The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and AFI 40-402, Protection of Human Subjects in Biomedical and Behavioral Research.

SOCIAL SAFETY NETS AND GENETIC ANTI-DISCRIMINATION IN PRIVATE LIFE AND INCOME REPLACEMENT INSURANCE

Anya Prince*

***University of Iowa College of Law**

Insurer use of genetic information has long been debated in the US and around the world. Although federal law prohibits health insurers from underwriting on the basis of genetic information, it does not address use by life, long-term care, and disability insurers. The debate in this area continues, highlighting tensions between social fairness concerns and the economic concerns of the insurance industry. The US, however, is not alone in its struggle to balance between business and social considerations. What can the US learn from the policies other countries have adopted to regulate insurer use of genetic information? This presentation will build on previous comparison work done on international policies, but specifically consider how a country's social safety net program affects the landscape of regulation of private life or income replacement insurers. On the one hand, outside the context of health insurance, the economic and social considerations of private, individually-written insurers is similar across countries. On the other, government programs in health, death benefits, and income replacement benefits alters, not just societies' attitudes towards solidarity, but also the potential impact of regulating insurer use of new technologies, such as big data and genetic test results.

FORENSIC BIOBANKING

Natalie Ram*

***University of Baltimore School of Law**

In March 2015, New Orleans filmmaker Michael Usry found himself the target of a police investigation stemming from a partial match between DNA left at a 1996 murder scene and Usry's father's DNA. Usry's father had submitted his DNA years earlier to a private laboratory for genealogical research. That laboratory's assets had subsequently been acquired by Ancestry.com, which made the database of genealogical genetic data publicly available. Investigators compared their crime scene DNA to the Ancestry.com database—of which Usry's father was a part—and discovered that the father was a close, but imperfect, match to the crime scene DNA. That match excluded Usry's father as a suspect but suggested that a close relative might have committed the crime. Based on the partial match, police began to investigate Usry, eventually securing a warrant for his DNA. Ultimately, Usry was cleared as a suspect when his DNA proved not to be a match for the crime scene DNA.

At present, little is known about whether and how criminal investigations gain access to genetic data held in clinical, research, and commercial biobanks. This paper investigates law enforcement use of genetic biobanks. First, it demonstrates that law enforcement access to and searches in genetic data held in biobanks is problematic, particularly in light of traditional bioethics principles, practical considerations concerning access to health care and participation in research, and criminal justice norms about who

properly ought to be subject to genetic identification through database search. Second, it details the panoply of legal sources that play a role in authorizing or constraining access to genetic resources, identifying multiple variables that impact privacy protection from forensic search. Third, it analyzes the complex interactions among these dimensions of variability to expose gaps in biobank privacy protection against law enforcement access—and identifies how these privacy gaps can most efficiently be remedied.

REGULATING THE DEAD: FROM PAST TO PRESENT

Alix Rogers*

***Stanford Law School**

Under contemporary American law most human corpses and some bodily parts are classified as quasi-property. Quasi-property is an American legal conception composed of limited interests that mimic some of the functions of property. It is a uniquely American idiosyncratic legal category that, while dismissed by many as a legal fiction, persists to this day. But where did quasi-property come from, and why did American courts ascribe quasi-property status to human remains? The question is particularly intriguing because quasi-property status broke with hundreds of years of inherited common law. Traditional explanations point to America's lack of ecclesiastical courts, which historically had jurisdiction over cemeteries and burial in England.¹ But historical examination reveals that this explanation does not sufficiently account for the initial application, dominance or persistence of the unique status of quasi-property. This paper argues that socio-cultural changes forged in the maelstrom of the Civil War precipitated the initial use and later systematic adoption by American courts of quasi-property status for human remains. Analysis of the rise of quasi-property in human remains at the turn of the nineteenth century is particularly significant because the nature of quasi-property rights in human remains is contentious and unsettled in contemporary legal analysis. Consequently, historical examination of the impetuses to its original application can shed new light on this contemporary debate.

IP PREPAREDNESS

Ana Santos Rutschman*

***DePaul University College of Law**

This Article introduces the concept of, and a framework for, intellectual property preparedness for outbreak diseases.

Through case studies on recent outbreaks (including Ebola and Zika in 2014-16), the Article begins by surveying the role of IP in responding to infectious diseases from the pre-outbreak to the post-outbreak stages. It identifies three types of IP inefficiencies that have historically affected this response: R&D failures, hold-up of pre-existing IP and licensing of emerging IP against the public interest. Cumulatively, these different types of inefficiencies have led to a recurring lack of IP preparedness—an ill-calibration of separate yet interacting features of the patent system—to respond effectively to infectious disease outbreaks.

The Article then turns to solutions to increase our IP preparedness for future outbreaks. In addition to new incentives streams, IP preparedness requires innovative legal measures to mitigate IP-related inefficiencies. The Article surveys existing mechanisms that can help accomplish this goal and lays out the ground for a new mechanism—a dormant license—to mitigate transactional IP inefficiencies when an outbreak occurs.

¹ Tanya K. Hernandez, "The Property of Death," *University of Pittsburg Law Review* 69 (1999): 971; P.D.G. Skegg, "Human Corpses, Medical Specimens and the Law of Property," *Anglo-Am. L. Rev.* 4 (1975): 412–425.

DELINKING REIMBURSEMENT

Rachel E. Sachs*

***Washington University in St. Louis School of Law**

Over the past few years, calls for the Food and Drug Administration (FDA) to approve pharmaceuticals more speedily have grown louder. At the same time, many have argued that America's drug pricing problems can be solved if only Congress gave Medicare the authority to negotiate drug prices. But scholars and policymakers have largely missed the linkage between these arguments. The FDA's regulatory system cannot be meaningfully changed without affecting the amount spent on pharmaceuticals, and Medicare's authority to negotiate drug prices depends on the FDA. This is true for a simple reason: FDA approval is often linked by law to insurance coverage. Insurers must cover most, if not all, FDA-approved drugs.

This Article first explains the link between FDA approval and insurance coverage, describing a range of insurance programs and analyzing what drugs they are legally required to cover. The Article then considers how the link between FDA approval and insurance reimbursement affects policy choices. For instance, proposals that would require the FDA to approve drugs on the basis of less robust evidence would result in the approval of more unsafe, ineffective drugs—and Medicare and Medicaid would need to cover all of them. Alterations to the FDA approval system without altering reimbursement requirements would increase costs, not decrease them.

The Article then envisions what the implications might be for both innovation and access if approval and reimbursement were delinked. There are at least three potential policy consequences, although their precise reach undoubtedly depends on the scope of delinkage. First, there would be some reduction in access to these medicines. If Medicare and Medicaid are not legally required to cover certain drugs, they will no longer choose to. But second, if companies know that they must earn coverage, perhaps by demonstrating efficacy over competitors, they may innovate in more socially valuable ways. Third, delinkage of this type would help address the drug pricing problem, precisely because of both of the above considerations.

Further empirical analysis will be needed before we can conclude as a policy matter that the benefits of delinkage outweigh the costs. But it ought to be part of the conversation, as it has the potential to address some of our innovation and pricing concerns while imposing minimal access constraints.

FRACKING HEALTH CARE: HOW TO SAFELY DE-MEDICALIZE AMERICA AND RECOVER TRAPPED VALUE FOR ITS PEOPLE

William M. Sage*

***School of Law and Dell Medical School, The University of Texas at Austin**

Call it the trillions that time forgot. Shining fortresses filled with gold and teeming with human activity dot the American landscape. Within them, much is produced to benefit the nation. Overseers enjoy prestige and prosperity, and minions security and purpose. Outside their gates, society's reverence is made tangible by regular custom and lavish tribute.

These fortresses are not feudal castles, grand cathedrals, or even great universities. They are emphatically not churning factories, although they are businesses. They are America's hospitals and clinics—the industrial engines of U.S. health care.¹ And most are both out of time and out of place.

Pushing \$4 trillion annually, and employing millions of people in most communities in every state, health care represents one-sixth of the American economy.² Only the automobile industry in its heyday during the

¹ See ROSEMARY STEVENS, IN SICKNESS AND IN WEALTH: AMERICAN HOSPITALS IN THE TWENTIETH CENTURY 40–46, 351–52 (1999) (asserting that not-for-profit hospitals have been profit-maximizing enterprises).

² Sean P. Keehan et al., National Health Expenditure Projections, 2016–25: Price Increases, Aging Push Sector To 20 Percent of Economy, 36 HEALTH AFF. 3553 (2017).

1950s and 1960s rivaled modern health care's centrality to peacetime domestic production and employment.³

In 2017, large economic sectors tend to share common features.⁴ Ownership is separated from control. Goods and capital move freely. Production is global and automated. Entry barriers have dropped. Products come assembled. Prices are low, as is inflation. Consumers matter. On the downside, domestic employment has slowed, and the rewards of production accrue mainly to senior executives and wealthy investors.⁵

Health care is different, a throwback.⁶ Ownership is either captive to or fused with control. Capital is hindered both entering and leaving. Entry barriers are substantial, even as consolidation accelerates. Technology seldom increases productivity. Trade is restricted and little production occurs offshore. Products are offered piecemeal at high and rising prices, often paid by intermediaries with faint consumer voice. But job growth is pronounced, and the artisanal and managerial classes prosper. Only higher education seems remotely similar, though (reproductive rights aside) health care has for the most part been spared parallel accusations of secular elitism.

Health care's privileged status imposes an unacceptable social cost. Sheltered by conscious if incremental public policy—including selective subsidies, entry restrictions, tax preferences, and protectionist professional self-governance—an estimated \$1 trillion each year is sacrificed in care that is overpriced, wasteful, useless, or harmful.⁷ At the same time, inattention to poverty, lack of education, and other “social determinants” of health compromises economic productivity and civic engagement, and adds substantially to the nation's medical bill.⁸

But there is more to this story than a plea for deregulation and the efficiency gains that would accompany it. The wealth trapped within American health care is simultaneously a tragedy and a miracle. It is a tragedy because stagnating wages, widening disparities in income, ballooning deficits, and stunted investments in education and social services make such medical profligacy shameful. It is a miracle because it still exists, whereas other resources of similar magnitude have already been dissipated without addressing any of the aforementioned failings—indeed, sometimes having contributed to them. It therefore can be released and used.

It is time to “frack” the health care system and innovate the de- medicalization of America. The catchphrase for this effort is assuredly not “Repeal and Replace,” the Republican party's oversimplified solution to the overblown criticism it continues to level against the Affordable Care Act. A better mantra is “Recover and Repurpose”—releasing the value trapped in our underperforming health care system and directing it toward more individually and socially productive ends. Significantly, this turns out to be a more complex and contextual project than putting one's faith in freedom and markets, although freedom and markets play a central role.

With careful planning and responsible execution, recovering and repurposing the trillions of dollars being spent on low-value medicine can set an example for policy-makers of an economic transition that offers broad distributive and communal benefits as well as efficiency gains. The current condition of American

³ Transportation in 1965 and health care in 1995 were similar in several ways: same shares of GDP, shares of employment, degrees of private control, high rates of avoidable death, and cultures of individual responsibility. See JERRY L. MASHAW & DAVID L. HARFST, *THE STRUGGLE FOR AUTO SAFETY* 50 (1990) (describing the cultural and economic power of the auto industry during its heyday).

⁴ For a persuasive description of globalization, see THOMAS L. FRIEDMAN, *THE WORLD IS FLAT: A BRIEF HISTORY OF THE TWENTY-FIRST CENTURY* (2005).

⁵ For an analysis of economic inequality and wage stagnation, see THOMAS PIKETTY, *CAPITAL IN THE TWENTY-FIRST CENTURY* (2014).

⁶ Cf. Susan Dentzer, *It's Past Time to Get Serious About Transforming Care*, 32 *HEALTH AFF.* 6, 6 (2013) (“One eternal mystery of US health care is why patients and payers have been loath to demand attributes they take for granted in other sectors of the economy, such as convenience, price transparency, and reasonable costs.”).

⁷ INST. OF MED., *BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA* 38 (Mark Smith et al. eds., 2013).

⁸ See generally ELIZABETH H. BRADLEY & LAUREN A. TAYLOR, *THE AMERICAN HEALTH CARE PARADOX: WHY SPENDING MORE IS GETTING US LESS* (2015) (discussing US lack of social investment); RICHARD COOPER, *POVERTY AND THE MYTHS OF HEALTH CARE*

REFORM (2016) (arguing that poverty, not clinical uncertainty, explains geographic variations in health care); Raj Chetty et al., *The Association between Income and Life Expectancy in the United States, 2001-2014*, 315 *JAMA* 1750 (2016).

politics compels such an approach. Cast in its best light, the cleavage revealed by the 2016 election cycle was not between the individual and the collective, or even between choice and coercion, but between re-invention and restoration. Moreover, the restorative forces made it clear that becoming “great again” meant recapturing many of the qualities that health care aberrantly if expensively has retained: jobs, nativism, regional fairness, paternalism, and trust.

CYBERPSYCHOLOGY

Julie Seaman*

***Emory University School of Law**

Since the birth and exponential growth of the Internet over the past two decades, a rapidly growing theoretical and experimental literature has sprung up and begun to study the effects of the online environment. With the emergence of the field of cyberpsychology over the past decade, as well as several academic journals solely devoted to computer mediated communication (CMC), the complex universe of the online social brain has begun to reveal itself. While much of this space is thus far only roughly mapped and much else is yet to be discovered, there are a number of preliminary findings that have implications for thinking about freedom of speech on the Internet. The nature and effects of disinhibition online, the effect of online social communication on memory and belief about facts and events in the physical world, the drivers of antisocial behaviors such as flaming, shaming, and trolling, the proliferation of gender-based online aggression, and the so-called “filter bubble” effect and its relation to social and political polarization are all fertile ground for analysis and further research as they relate to First Amendment theory, doctrine, and values.

In this essay, we hazard our first and very tentative steps into this varied and treacherous terrain at the crossroads of the First Amendment, social media, and human behavior. We proceed from an interdisciplinary perspective, considering research in various subfields of psychology, anthropology, and political science. Our overall framework, however, draws on the evolutionary science of group dynamics and cooperation, which has much to say about how individuals behave within groups, how groups behave with respect to other groups, and the features that can make some groups successful, constructive, egalitarian, and prosocial while others are destructive, hierarchical, violent, and antisocial. In particular, we draw on the Nobel Prize-winning work of Elinor Ostrom regarding the eight fundamental design principles that underlie successful group management of common resources and the extension of that work to other types of groups trying to accomplish other goals. We then explore the implications of these ideas as they relate to groups that operate in cyberspace.

BLUEPRINT FOR A NEUROLAW CLINIC

Francis X. Shen*

***University of Minnesota Law School**

Legal scholarship at the intersection of neuroscience and law is rapidly increasing. But at present, the practical implications of neurolaw remain mostly speculative. I argue in this article that this is large part because we do not (yet) have a mechanism by which students can be taught how advances in neuroscience (and related fields) can be readily integrated into real legal cases. Thus, I develop here a “Blueprint for a Neurolaw Clinic.” In Part I, the Article discusses the rationale and benefits of a Neurolaw Clinic. I discuss how a Neurolaw Clinic would operate differently than traditional clinics. Rather than take a single case from start to finish, a Neurolaw Clinic would work collaboratively with the Law School’s existing clinics. Part II presents seven use cases, highlighting ways in which a Neurolaw Clinic could enhance existing clinical work in: (1) juvenile justice, (2) criminal defense, (3) civil litigation, (4) immigration, (5) family law, (6) elder law, and (7) domestic violence. Part III addresses a series of critiques and design considerations. I argue that ideally a Neurolaw Clinic would be part of a larger Law and Biosciences Clinic, with additional expertise

in related bioscience fields. Part IV concludes, arguing that the Law School that moves first to create a Neurolaw Clinic will reap significant dividends.

GENETIC DATA, TRADE SECRETS, AND PUBLIC RESEARCH: ADAPTIVE IMMUNORECEPTOR REPERTOIRE PROJECTS

Jacob S. Sherkow*

***New York Law School**

The human immune system is dynamically adaptive: it responds, on the fly, to unknown and unforeseen foreign invaders through the regulation of gene expression in a variety of cell types. In particular, “immunoreceptors”—complex proteins attached to B- and T-cells—attach to foreign material, i.e., “antigens,” and signal the immune system to respond. The repertoire of these immunoreceptors is galactically diverse. Each individual possesses billions of different immunoreceptors, each binding to its own antigen; across humanity, the number of different possible immunoreceptors likely numbers into the trillions.

Recent high-throughput gene sequencing technology has now made it possible to sequence the entirety of an individual's immunoreceptor repertoire. Scientists from around the globe are now working in concert to understand the diversity and function of the “adaptive immunoreceptor repertoire,” or AIRR. But the enormous volumes of data produced by such projects raise difficult questions concerning trade secrecy. Some data within such AIRR repositories may be incredibly valuable in the development of human therapeutics. Researchers have accordingly struggled with whether, how, and to what extent, such information must be disclosed to the public or whether such information, in some circumstances, can be preserved as a trade secret. This is all the more complicated given the global nature of such efforts: an AIRR research group frequently spans multiple jurisdictions, with varying rules regarding trade secrecy, patenting, and researchers' responsibilities to release their data.

This chapter will briefly recount the science concerning AIRR and community efforts to regulate it by private governance, namely, the community AIRR project, or CAIRR. The chapter will then provide an overview of differences in trade secret protection for research data across several jurisdictions where such research is taking place, including the Europe, the United Kingdom, Canada, and the United States. And the chapter will conclude by suggesting best practices for implementing trade secrecy for cross-border AIRR projects.

CONTEXTUALIZING THE INFORMATION-FACILITATING FUNCTION OF PATENTS THROUGHOUT THE INNOVATIVE PROCESS

Brenda M. Simon*

***Thomas Jefferson School of Law**

Patents are often critical to facilitating information exchange during the innovative process, yet their role has not been clearly articulated. Traditional understanding of the role of patents in enabling the exchange of information has focused primarily on entities in two industries—biotechnology and software. This Article seeks to provide a more complete account of the disclosure-enabling function of patents throughout the innovative process by providing a richer account of a critical, yet often-overlooked area—the medical device industry—by evaluating existing literature and describing the results of a series of interviews conducted with medical device professionals from small and medium sized firms. In addition to considering the perspective of inventors, which has often been the focus of recent scholarship, this Article also sets forth the viewpoint of investors and commercialization partners. The medical device industry can operate as a barometer of how well the patent system in general is functioning in accordance with its historic purpose—to promote progress through innovation.

Patents may play a very different role in the initial stages of discussion with prospective investors than during later attempts to structure commercialization alliances. The extent to which patents encourage the

exchange of information about an invention by mitigating the risk of expropriation depends on many considerations. For example, the nature of the invention, relationship between the parties, and whether the inventors can retain tacit knowledge essential to executing the invention and disclose information in stages can affect how patent protection enables information exchange. In the medical device industry, for example, innovators seeking to protect traditional mechanical inventions from expropriation may depend on different mechanisms than they might otherwise use to protect devices that have a strong software or data-generating component.

The function of patents in encouraging information exchange between potential partners during the later stages of coordinating commercialization is similarly highly-contextual. For companies that are not integrated, patents can provide a mechanism to allow for increased scaling and coordination with commercialization partners, providing greater flexibility in determining organizational structure and mitigating the risks of expropriation. From the perspective of potential commercialization partners, patents can provide reassurance against expropriation risks by unrelated parties. The availability of patent protection may also promote synergistic exchanges of information in the development process. As an example, in the medical device field, over 80 percent of companies have fewer than 50 employees, they frequently rely on alliances to manufacture and market their products, and their commercialization partners rely on intellectual property to prevent expropriation by third parties.

By providing a descriptive timeline of the innovative process through a closer examination of the largely overlooked medical device industry, this Article sets forth a more complete account of the circumstances in which patents may enable information exchange and when they may be less necessary, elucidating the larger narrative of innovation and the role of patents in it.

GINA AND EDITED GENOMES

Andrew W. Torrance*

***University of Kansas School of Law**

The Genetic Information Nondiscrimination Act (“GINA”) became law on May 21, 2008. In the decade since, it has changed the way employers and health insurers operate because it forbids their use of genetic information from individuals in making decisions concerning employment or insurance coverage of those individuals. Approximately 200 disputes arising from GINA have led to litigation yielding published opinions. These range from the mundane, such as disputes over asking employees for their family medical histories, to the profane, such as the mysterious case of the “devious defecator”. All of these disputes have involved information preëxisting in unaltered “natural” genomes. With the advent of gene editing, the prospect of GINA’s application to edited genomes presents itself. This article provides an introduction to gene editing, particularly in humans, explores how relevant GINA may be to the protection of the privacy of genetic information derived from edited genomes, and offers perspectives on whether and how GINA might be amended to achieve its original goals of genetic nondiscrimination.

CHANGING THE COMPANY TO CHANGE THE RESULTS: APPLICATION TO THE OPIOID EPIDEMIC

Liza Vertinsky* & Yaniv Heled

***Emory University School of Law**

There is increasing evidence that the current levels of opioid use and abuse can be attributed at least in part to actions taken by pharmaceutical companies seeking to maximize their returns on sales of opioids (and now on antidotes to overdoses of opioids). Many of these corporate actions are not illegal, and those activities that might run afoul of the law involve behavior that is difficult to detect and monitor. In an earlier paper we have documented the pervasive disconnect between private incentives and public needs in healthcare markets, and we have argued that healthcare companies should be strongly incentivized, if not required, to be (come) benefit corporations in order to inject the public interest more directly into corporate

decision making. We now show how such a measure could be used to more effectively address and curtail the corporate abuses that have contributed to the current opioid epidemic.

The article begins with a study of corporate contributions to the abuse of opioids in the U.S. It focuses on the incentive structures that have propelled companies into the business of mass marketing opioids through a variety of channels extending far beyond direct advertising, along with the market structure that allows and even facilitates such corporate strategies. It goes on to examine current measures to enforce reforms, including law suits by the attorney generals in a number of states and some modest efforts at internal corporate reforms in the shadow of such lawsuits. It concludes by examining the limitations of existing approaches and the opportunities for a more effective response through change in the corporate form itself.

DATA ACCESS POLICIES AS A RISK MITIGATION STRATEGY

Jennifer K. Wagner*

*Center for Translational Bioethics & Health Care Policy, Geisinger

Introduction: The meaning and contours of the “loss of chance” doctrine in the context of precision medicine are nebulous at best. Precision health initiatives launched by health providing organizations enable biomedical researchers (who often do not provide health care services personally and are not licensed to do so) to conduct broad discovery research involving examination of electronic health records, whole genome or exome sequencing data, and nontraditional “health data” sources to address social and environmental determinants of health along with biological determinants. These initiatives sometimes return of genomic results deemed by the institution or researchers to be “medically actionable” back to the patient-participants and their doctors. Genetic professionals have long been concerned about legal liability, including liability risks that might attach when decisions are made to return or, alternatively, withhold data or results from individuals to whom those pertain. Labs do not routinely reanalyze data or recontact individuals with updated information as genomic science and technology advance, and there is general consensus that researchers do not have duties to look for or report all findings to participants. Nevertheless, when broad genomic research is conducted where participants are also patients and when institutional policy or research protocol stipulates data or results will be withheld (regardless of rationale), there are concerns about when and how individuals might ultimately learn this information and whether the discovery will be too late to avoid (1) the progression of a condition for which prevention or treatment was available or (2) unnecessary harms such as ineffective treatments for which substitutes were available. The loss of chance doctrine is a legal theory available in some states that, in the context of medical malpractice, enables a plaintiff to recover from a defendant whose breach of duty reduced the chance of a favorable outcome (such as a delayed diagnosis or treatment resulting in diminished chance of recovery or survival). There is a paucity of critical analysis of this legal doctrine, despite acknowledgment by some of its relevance to the genetics field. Even the American Law Institute has not yet taken a firm position, despite the doctrine’s first court appearance 50 years ago. The ELSI community has been fixated on the preliminary issue of whether researchers have a duty to return genomic results to participants. Its general consensus that researchers generally do not have a legally recognized obligation to return data and results to research participants is an important one; nevertheless, it does not settle the legal inquiry. **Methods:** Using the WestlawNext® legal database, a systematic search of cases invoking the “loss of chance” doctrine was performed. Of the search results, cases that had occurred in jurisdictions served by the U.S. Court of Appeals for the Third Circuit (*i.e.*, Pennsylvania, New Jersey, Delaware, and U.S. Virgin Islands) were further analyzed using standard legal research methodologies. **Results:** A total of 872 cases involving the “loss of chance” doctrine was identified, including 605 reported and 267 unreported cases. Among them were 185 federal and 687 state cases (of which 99 and 506 were reported, respectively). Seventy (or 8%) of the cases identified were located in jurisdictions of interest and further analyzed. No cases were decided by the U.S. Supreme Court, U.S. Court of Appeals for the Third Circuit, or Virgin Islands District Court. Forty-one of the 70 cases subjected to further examination (or 59%) were reported, with 19 in PA, 33 in NJ, and 19 in DE. **Discussion:** This preliminary legal analysis revealed that the “loss of chance” doctrine is poorly understood, inconsistently articulated, and manifested differently across jurisdictions within the medical malpractice context. In light of the legal uncertainty and given the perceived burdens making ongoing reanalysis and recontact of all genomic research patient-participants infeasible, the adoption of

institutional policies to provide patient-participants with *prompt and full* genomic data access—regardless of whether those data are CLIA-generated or confirmed—as a risk mitigation strategy is an attractive option worthy of consideration.

Conflicts of Interest: The author has no conflicts of interest to disclose for this work.

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Note: I presented some of this work as a poster at the 2017 ASHG Annual Meeting in Orlando, FL; however, I'm eager to obtain critiques and suggestions from my Bio-Law colleagues on how I can improve my analysis (which to date has been admittedly basic) and develop a more sophisticated understanding and discussion so that the work is worthy of publication. I particularly am seeking discussion regarding how to examine institutional obligations to patient-participants.

ACCESS TO PHYSICIAN AID IN DYING FOR PERSONS EXPERIENCING MENTAL DISORDERS OR PSYCHOLOGIST DISTRESS: A LEGAL AND BIOETHICAL ANALYSIS

Lois A. Weithorn*

*UC Hastings College of Law

At the time of this writing, six states and the District of Columbia permit individuals to receive physician assistance in hastening death under limited circumstances. In 1997, after overcoming multiple legal challenges, Oregon's statute became the first such law to go into effect in the U.S. Over a decade later, Washington followed. Eventually, four more jurisdictions (Vermont, California, Colorado, and the District of Columbia) enacted physician aid in dying legislation. Montana's Supreme Court legalized physician aid in dying in 2009.

There is substantial similarity among the statutory frameworks in imposing significant restrictions on patients' access to state-authorized aid in dying. For example, the statutes condition eligibility on medical certification that the patient has a "terminal" medical condition with a life expectancy of no more than six months. The patient must be judged to be "competent" to make this decision and physically capable of self-administering the lethal prescription.

In addition to a determination of competence, some statutes, such as California's, also require that the evaluating physician refer the patient to a mental health professional for assessment "[i]f there are indications of a mental disorder..."¹ While additional language in California's statutes suggests that the role of the mental health assessment is to provide further elucidation about questions of the patient's competence and a determination that "the individual is not suffering from impaired judgment due to a mental disorder,"² there remains a lack of clarity as to the effect that a diagnosis of a mental disorder or psychological symptomatology has on patient eligibility. One interpretation suggests that if a patient meets legal criteria for competence to make treatment decisions,³ other psychological factors are not pertinent to one's eligibility for such assistance. Alternatively, a broader construction of the concept of "impaired judgment" may exclude some persons who meet technical competence standards.

This talk will briefly analyze the legal, bioethical, and psychological issues related to eligibility for physician aid in dying of persons with mental disorders and other forms of psychological distress. It will address current debates about the impact of mental disorder on decisional competence, particularly in the context

¹ Cal. Health & Safety Code §443.7(d) (2018).

² Cal. Health & Safety Code §443.8(c) (2018).

³ Empirical research published in the 1990s and thereafter has provided powerful evidence to help counter an assumption that persons with mental disorders are categorically incompetent to make treatment decisions. Yet, the line between competence and incompetence is not always clear, particularly when the stakes of a determination are as dramatic as life or death.

of end of life decisionmaking. The author will close with recommendations regarding application of physician aid in dying statutes to persons diagnosed with mental disorders or serious psychological distress.⁴

RISKS AND LEGAL PROTECTIONS IN LARGE-SCALE GENE-ENVIRONMENT INTERACTION STUDIES

Leslie E. Wolf*

***Georgia State University College of Law**

Large-scale gene-environment interaction studies, such as the Precision Medicine Initiative, offer unparalleled, innovative opportunities to learn more about human health and disease, but raise critical concerns about protections against research risks. Traditional approaches to protecting research participants may not address new or heightened risks in the “big data” era, and the strengths and weakness of the “web” of protections federal and state laws create is poorly understood. Moreover, emerging models that cede control to participants over whether, with whom, and for what purposes their data are shared may fall outside some of these protections.

Our legal research elucidates the web of legal protections, including laws governing human subjects research, privacy, consent, discrimination, and use of research participants’ genetic information. It has revealed substantial regulatory activity and variation across the 50 states that may fill gaps in federal protections. For example, some states go further than the Genetic Nondiscrimination Act (GINA) by extending genetic antidiscrimination statutes to life and disability insurers or to employers with less than 15 employees. In addition, states often explicitly provide remedies, such as statutory damages, attorneys’ fees, and costs that can facilitate enforcement of legal rights not afforded in federal laws. This state activity can strengthen the rights and protections afforded to some participants, but can leave other participants unprotected simply because of where they live, entered the study, or where their data was collected or stored.

Note: This presentation comes out of funded research (NIH R01 - HG - 007733, PI: Laura Beskow) in collaboration with colleagues at Duke University. The Georgia State team leads the legal analysis and also includes Professor Erin Fuse Brown, as well as our excellent GRAs.

STATE EFFORTS TO ADDRESS DRUG-PRICING CONTROVERSIES

Rebecca E. Wolitz*

***Stanford Law School**

Public ire over the high costs of pharmaceuticals is well-known. Members of Congress and the new administration both have stated that this issue merits attention. However, in an uncertain federal environment and with lingering questions about the authority and expertise of federal agencies to address drug- pricing controversies, it is important to consider the role of states.

States have, in fact, been taking matters into their own hands. State legislative activity has surged on this issue. States from California and Nevada in the West to Maryland and New York in the East are experimenting with new bills and laws to address drug-pricing controversies.

⁴ This work is an outgrowth of the author’s consulting relationship with the Center for AIDS Prevention Studies, University of California, San Francisco. An earlier presentation examined implications of California’s End of Life Options Act for persons living with HIV. My research revealed that the most salient factor needing attention for such persons relates to the psychological distress and psychosocial isolation experienced by many long-term survivors of HIV. Some of these individuals, stable on antiretroviral therapy for decades, choose to stop taking their medications in order to meet the six-month life expectancy requirement of the statutes and receive physician assistance to hasten death. Such cases have proven challenging for those applying the statutes.

Yet, despite how they are often discussed, drug-pricing controversies appear to have different underlying causes and consequently implicate different kinds of policy considerations. And, interestingly, close inspection of recent state efforts reveals that states have different kinds of controversies in their crosshairs. Among others, state proposals have included increasing pricing transparency, regulating drug prices, and limiting costs through restrictions on payment. Some of these efforts have a specific focus—for instance on a specific disease type or on generics.

These observations lead to two important and fundamental questions: First, what role *can* states play with respect to addressing drug-pricing controversies? Second, what role *ought* states to play with respect to addressing drug-pricing controversies?

This paper will tackle these broader legal and normative questions by focusing on a subset of issues, including the narrower issue of state price regulation of patented pharmaceuticals. With respect to the legal issue of whether states have the legal ability to regulate the prices of patented medications, there is currently one precedent directly on point: *Biotechnology Industry Organization v. D.C.*, 496 F.3d 1362 (Fed. Cir. 2007). This Federal Circuit case considered the District of Columbia's Excessive Pricing Act and ultimately deemed the Act to be conflict preempted. As will be argued, this ruling is questionable for a number of reasons.

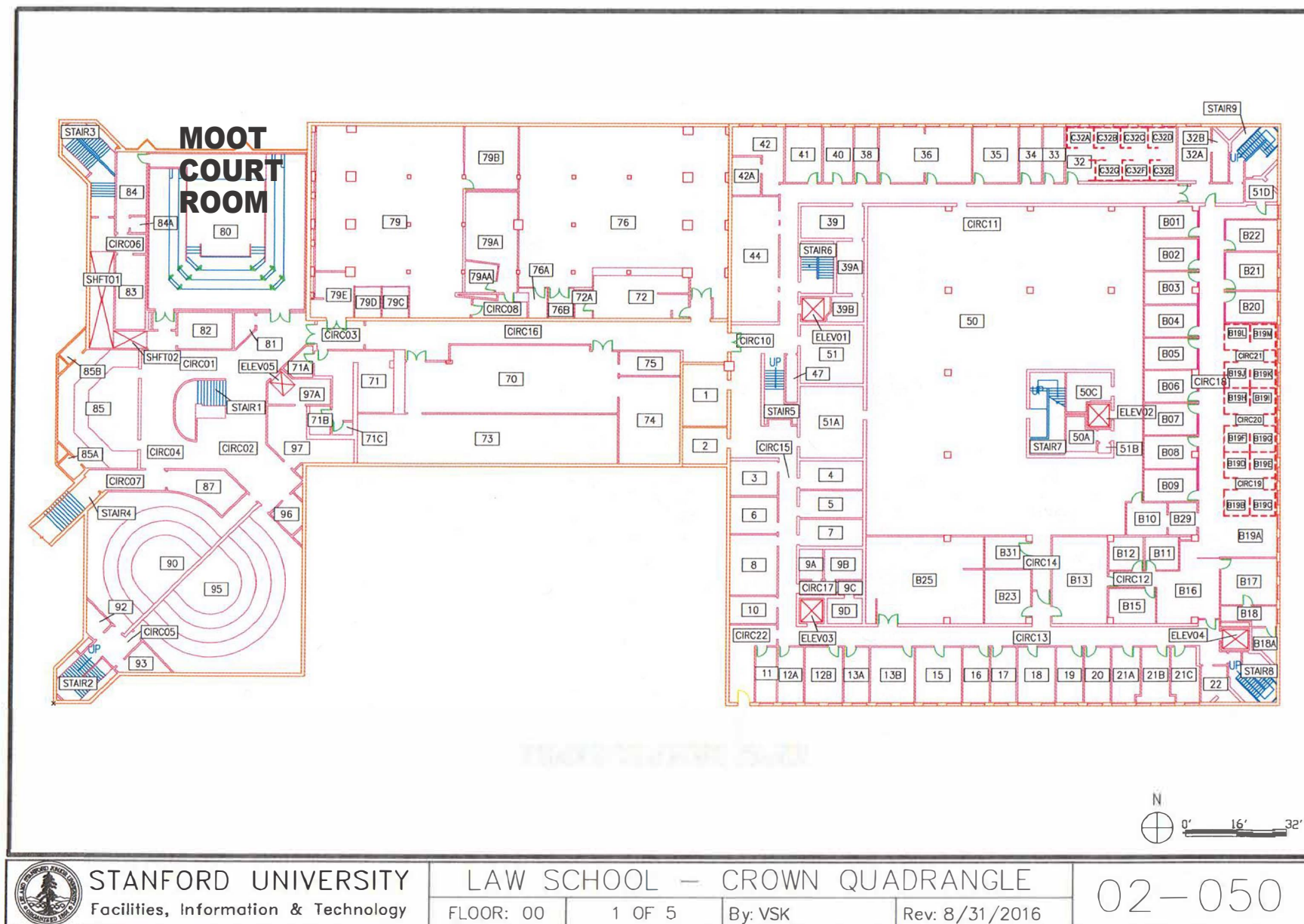
Whatever one thinks about the legal questions, however, normative questions remain. Particularly given the intersection of drug-pricing controversies with issues of innovation policy and consumer access, what role ought states to play in addressing drug-pricing controversies? After taking account of legal ability and authority, how should we begin to think about the appropriate role of federal versus state efforts in this space? This paper will explore and address these crucial questions.

GOOD GATEKEEPING

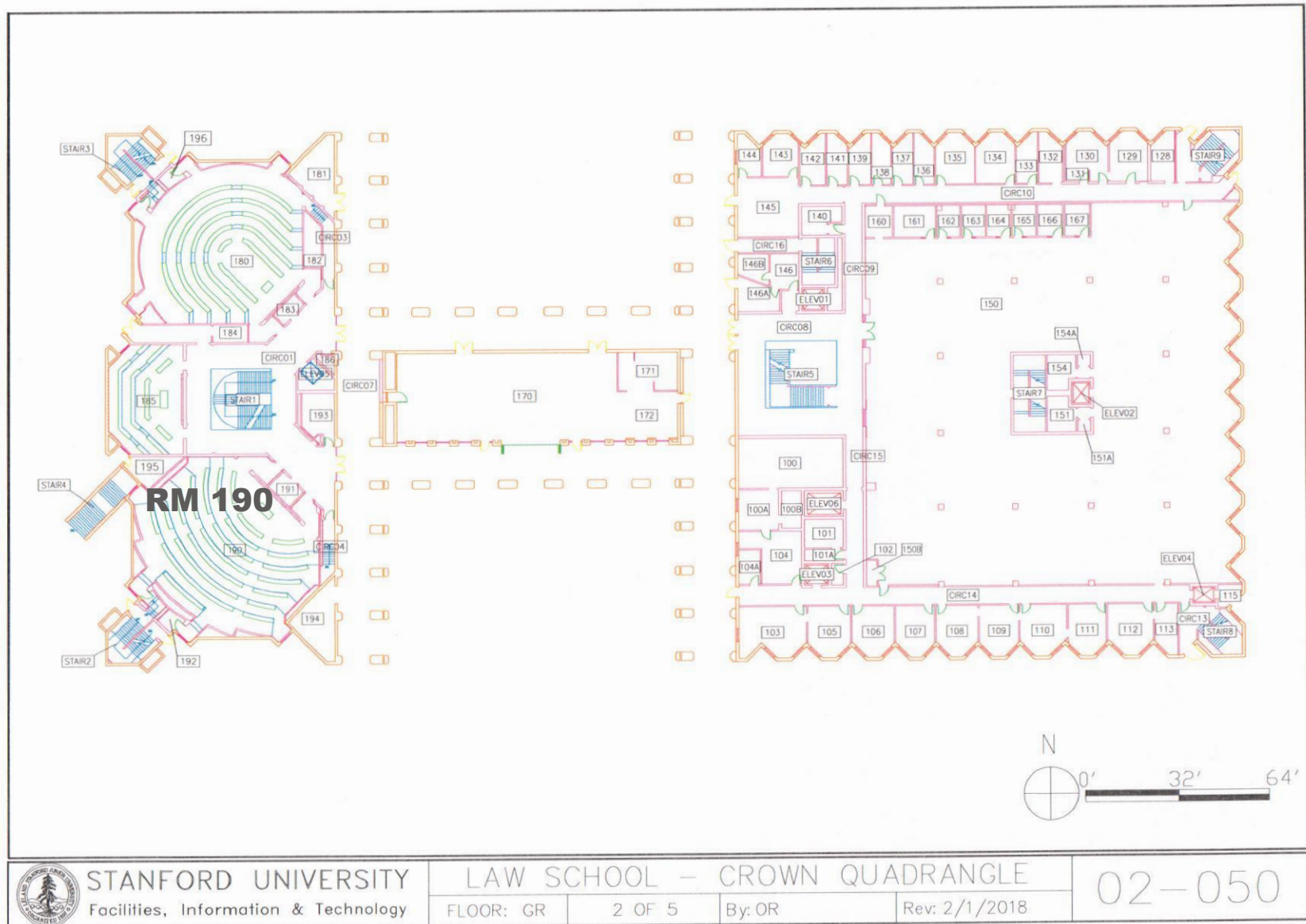
Patricia J. Zettler*, Margaret Foster Riley, & Aaron S. Kesselheim

***Georgia State University College of Law**

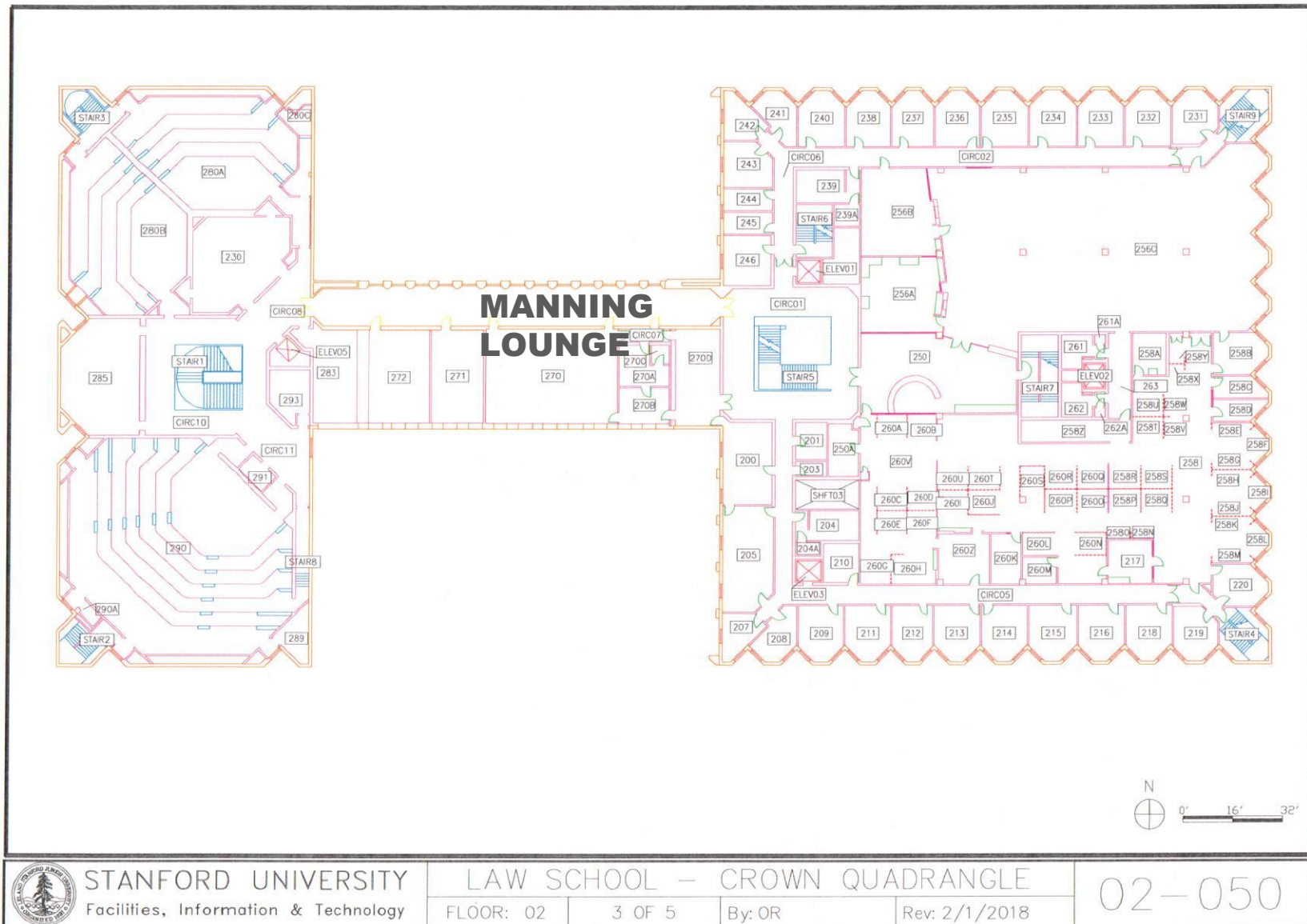
The Federal Food, Drug, and Cosmetic Act (FDCA) requires authorization from FDA to market various products, including new drugs for humans and non-human animals, many devices, and new tobacco products. Although the precise standards for marketing authorization for product categories differs, common to the FDA's gatekeeping role for each is a weighing of the products' risks and benefits. Yet, in part because the FDCA defines drugs, devices, and tobacco products quite broadly, this weighing of risks and benefits is done for products with very different characteristics—including products traditionally understood to be therapeutic and subject to FDA gatekeeping (e.g., cancer drugs), products intended for enhancement (e.g., non-invasive devices used for cognitive enhancement), and “vice” products used for recreation (e.g., vaping products or recreational marijuana). This project explores how the FDA has interpreted the statutory standards for marketing authorization for products with such different kinds of risks and benefits. It draws on relevant FDA and administrative law literature and caselaw to analyze the extent to which the FDA can and should interpret its gatekeeping role as being the same or different for therapeutic, enhancement, and vice products, regardless of whether such products are drugs, devices, or tobacco products.



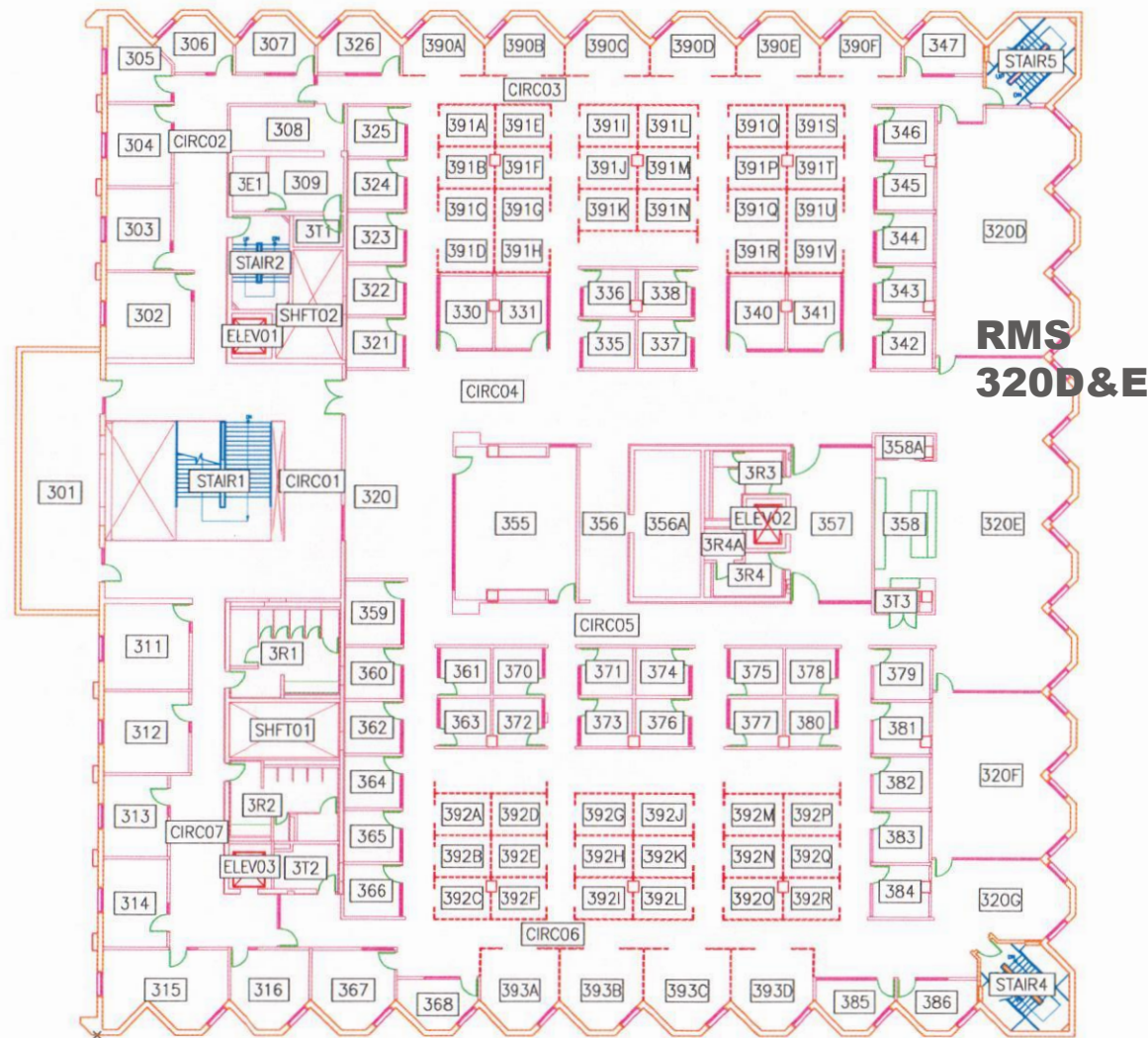
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